

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 132<sup>nd</sup> Institutional Ethics Committee** meeting held on 26<sup>th</sup> May 2023, at 2:30 PM, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

**Present:**

1. Prof. M. K. Mitra, Retd. Professor, Dept. of Medicine, KGMU, Lucknow	Chairperson
2. Prof. S. P. Ambesh, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Ex-Officio Member
3. Dr. Gautam Palit, Former Chief Scientist and Head, Dept. of Pharmacology, CSIR, Lucknow	Member
4. Dr. Arun Chaturvedi, Retd. Head, Dept. of Oncology, KGMU, Lucknow	Member
5. Dr. Mala Kumar, Professor, Department of Pediatric, KGMU, Lucknow	Member
6. Dr. Uday C. Ghoshal, Prof. & Head, Department of Gastroenterology, SGPGI MS, Lucknow	Member
7. Dr. Vinita Agarwal, Professor, Department of Pathology, SGPGIMS, Lucknow	Member
8. Prof. Anand Vishwakarma, Professor of Law and Director Legal Cell, University of Lucknow	Member
9. Shri. Vijai Varma Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
10. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
11. Shri Sharad Jain, Shri Madhav Seva Ashram, Lucknow	Member
12. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
13. Mr. Anil Kumar Srivastava, Retd. Professor, Department of Sociology, University of Lucknow	Member
14. Dr. Shagun Mishra, Additional Professor, Department of Radiotherapy, SGPGIMS, Lucknow	Alternate Member Secretary
15. Dr. Durga P. Misra, Associate Professor, Department of Clinical Immunology, SGPGIMS, Lucknow	Member Secretary

**Determination of quorum:** quorum was complete: 15 members present, with 10 non-institutional members.

**A: General discussions and confirmation of Minutes:**

**Approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 131<sup>st</sup> IEC meeting held on 12.05.2023. All the members of IEC approved the minutes of the meeting.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**B. Review of New Proposals:**

**Agenda No. 1**

**IEC code:** 2023-132-PhD-132

**Type of submission:** Project PhD

**Title of project:** Clinical, neurophysiological and metabolomic studies in the patients with subacute combined degeneration.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

Primary reviewer (Technical): Dr. Uday C. Ghoshal

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Is a repeat CSF study indicated at three months? Please clarify

The CV of external co-investigator Dr Bikash Baishya is incomplete

In the PID:

1. Please clarify that the patient shall not be charged for extra tests being conducted for the purpose of the study alone.

2. The PID should be different for patients and for healthy controls

3. In the PID for the guardian/LAR, "you" has to be changed to "your relative/ ward/ patient"

Decision: Minor revision

**Agenda No. 2**

**IEC code:** 2023-133-IMP-132

**Type of submission:** Project Intramural

**Title of project:** DEVELOPMENT AND VALIDATION OF MULTI-PLEX REAL-TIME PCR FOR ASSESSMENT OF TRANSCRIPTIONAL VARIABILITY OF HPA ALLELES

**PI:** Dr Dheeraj Khetan

**Department:** Transfusion Medicine

Primary reviewer (Technical): Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

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**Present:**

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4. Dr. Arun Chaturvedi, Retd. Head, Dept. of Oncology, KGMU, Lucknow	Member
5. Dr. Mala Kumar, Professor, Department of Pediatric, KGMU, Lucknow	Member
6. Dr. Uday C. Ghoshal, Prof. & Head, Department of Gastroenterology, SGPGI MS, Lucknow	Member
7. Dr. Vinita Agarwal, Professor, Department of Pathology, SGPGIMS, Lucknow	Member
8. Prof. Anand Vishwakarma, Professor of Law and Director Legal Cell, University of Lucknow	Member
9. Shri. Vijai Varma Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
10. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
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The CV of external co-investigator Dr Bikash Baishya is incomplete

In the PID:

1. Please clarify that the patient shall not be charged for extra tests being conducted for the purpose of the study alone.

2. The PID should be different for patients and for healthy controls

3. In the PID for the guardian/LAR, “you” has to be changed to “your relative/ ward/ patient”

Decision: Minor revision

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**Department:** Transfusion Medicine

**Primary reviewer (Technical):** Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved



**Lt Col Varun Bajpai VSM**  
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SGPGIMS, Lucknow

**Agenda No. 3**

**IEC code:** 2023-134-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Cardiovascular transition in late preterm & term neonates during early postnatal period (first 72 hours of life):A prospective observational study

**PI:** Dr Anita Singh

**Department:** Neonatology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

PID point number 6: “palan kiya jayega” should be “nigrani ki jayegi” or “nirakshan ki jayegi”

Consent form should have the name of the subject with their father’s/ mother’s name

Is it date of enrollment or date of birth? Please clarify and use the same in both English and Hindi ICFs.

Remove the first line on the PID. “Kindly refer to Table 3.2 for the essential elements of an informed consent document. For example, of PID in non-interventional studies, see appendix (AP7/V3). For ‘Recommended Terms for use in Informed Consent Document’, see appendix (AP12/V3)”

Point 14 of PID: the response is not appropriate. The details of what would be done should be provided. Please rewrite this part of the PID in its entirety.

The **contact** details of PI are required (not that of the student – this should not be mentioned). Also, the contact details of member secretary IEC with the official landline number of IEC should be mentioned.

Decision: Minor revision

**Agenda No. 4**

**IEC code:** 2023-135-EMP-132

**Type of submission:** Project Extramural

**Title of project:** Assessment of changes in Liver stiffness measurement and METAVIR fibrosis stage after endovascular Intervention in Budd-Chiari Syndrome.

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The study should be initiated only after securing funding so that the extra tests done for the purpose of research only are not charged to the patient.

In the paragraph 5 of the PID, please use the correct Hindi translation for “follow-up course”

Please provide informed consent forms in both English and Hindi.

Decision: Minor revision



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**Agenda No. 5**

**IEC code:** 2023-136-IMP-132

**Type of submission:** Project Intramural

**Title of project:** Anthropometric measurements and analysis of the Auricle and determination of the age of maturity of the ear in the Indian population

**PI:** Dr Anupama Singh

**Department:** Plastic Surgery

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

PID should mention "your child is being invited" (not "you are being invited")

Decision: Minor revision

**Agenda No. 6**

**IEC code:** 2023-137-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** 68 Ga FAPI PET/CT as a potential tool for assessing liver fibrosis in chronic liver disease: A pilot study

**PI:** Dr Manish Ora

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Is the product being used approved for this indication by regulatory authorities? Please clarify

Please clarify whether the cost of the procedure has to be borne by the patient.

Decision: Minor revision

**Agenda No. 7**

**IEC code:** 2023-138-PDCC-132

**Type of submission:** Project SRF/PDF/PDCC

**Title of project:** Study of clinico-pathological profile of skeletal oligometastatic breast cancer and its management outcomes

**PI:** Dr Gyan Chand

**Department:** Endocrine Surgery

Primary reviewer (Technical) Dr. Durga P. Misra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The waiver of consent form is incomplete. Please provide a complete form.

Highlight the importance of the study in the revised protocol.

Decision: Minor revision

**Agenda No. 8**

**IEC code:** 2023-139-MCh-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Patient perspective on Oncoplasty (reconstruction) Vs BCS ( WLE) Vs MRM following video counselling using story telling technique with animation characters

**PI:** Dr Sabaretnam Mayivaganan

**Department:** Endocrine Surgery


Primary reviewer PID and CF: Dr. Shagun Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 9**

**IEC code:** 2023-140-IP-132

**Type of submission:** Project Independent

**Title of project:** Bile Acid Synthetic Defects: Clinical Profile and Natural History

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr. Uday C. Ghoshal

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved

**Agenda No. 10**

**IEC code:** 2023-141-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Prevalence of neuropsychiatric manifestations and delirium in Lupus

**PI:** Dr Able Lawrence

**Department:** Clinical Immunology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The patient information document should be expanded. At present, it appears to be too brief.

The PID for control mentions "you are a patient with SLE". Please modify this.

The PID for control should not mention standard of care as this is likely not relevant for a control subject.

Decision: Minor revision

**Agenda No. 11**

**IEC code:** 2023-142-EMP-132

**Type of submission:** Project Extramural

**Title of project:** Tofacitinib/ Sirolimus in refractory Still's disease

**PI:** Dr Anu Balakrishnan

**Department:** Clinical Immunology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Is tofacitinib/ sirolimus approved by the DCGI for use in children between 16-18 years? Please clarify.

The PID should be provided in a structured format as this is a clinical trial.

The PID should clarify who shall pay for the drug and for adverse reactions arising from the use of the drug.

The PID should mention what adverse events can occur with the drug and whether these adverse events can be treated.

Decision: Minor revision



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**Agenda No. 12**

**IEC code:** 2023-143-IP-132

**Type of submission:** Project Independent

**Title of project:** Three dimensional reconstruction of the congenital cleft of ear lobule with lipodermal flap

**PI:** Dr Anupama Singh

**Department:** Plastic Surgery

Primary reviewer (Technical): Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

It appears that your project has already been completed. The IEC considers projects before the work has been initiated. Completed work is not under the purview of the ethics committee for review.

**Agenda No. 13**

**IEC code:** 2023-144-IP-132

**Type of submission:** Project Independent

**Title of project:** correction of long standing flexion contracture of digits with surgical release and distraction histogenesis

**PI:** Dr Anupama Singh

**Department:** Plastic Surgery

Primary reviewer PID and CF: Dr. Shagun Misra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

It appears that your project has already been completed. The IEC considers projects before the work has been initiated. Completed work is not under the purview of the ethics committee for review.

**Agenda No. 14**

**IEC code:** 2023-145-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Comparison of Performance Characteristics of LMA ProSeal® and LMA BlockBuster® in Children Undergoing Surgical Procedures Under General Anaesthesia: A Randomized Control Study

**PI:** Dr Ashish Kumar Kannaujia

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The proposed project is a Randomized Controlled Trial comparing Oropharyngeal Leak Pressures(OLP) of two LMA devices for administering GA to children.

- The RCT is being conducted on children aged 1 to 12 years and will require permission from parents/LAR and documentation of verbal/oral assent for children 7-12 years of age in the presence of parents/LAR.

- Suggest adding a flow chart as per the SPIRIT guidelines for clinical trial protocols.

- Suggest adding details of primary statistical analysis planned for hypothesis testing.

Decision: Minor revision



**Lt Col Varun Bajpai VSM**  
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SGPGIMS, Lucknow



**Agenda No. 15**

**IEC code:** 2023-146-IP-132

**Type of submission:** Project Independent

**Title of project:** Comparison of clinical and laboratory features of children with Acute Viral Hepatitis and acute hepatitis due to Tropical Infections

**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr. Uday C. Ghoshal

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

**Statement assuring the right of participants is not violated is missing from the waiver of consent form. Please provide the completed waiver of consent form.**

Decision: Minor revision

**Agenda No. 16**

**IEC code:** 2023-147-IP-132

**Type of submission:** Project Independent

**Title of project:** Late onset Lupus Nephritis- A clinico-pathological and outcome study from a single centre in India

**PI:** Dr Anupama Kaul

**Department:** Nephrology

Primary reviewer (Technical) Dr. Durga P. Misra

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

Decision: Approved

**Agenda No. 17**

**IEC code:** 2023-148-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Randomized placebo-controlled trial of Psyllium fiber in functional abdominal pain disorders in children

**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved



**Lt Col Varun Bajpai VSM**  
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SGPGIMS, Lucknow

**Agenda No. 18**

**IEC code:** 2023-149-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** To study the effect of propofol with or without dexmedetomidine on optic nerve sheath diameter (ONSD) in robot-assisted pelvic laparoscopic surgeries: A randomized trial

**PI:** Dr Sandeep Sahu

**Department:** Anaesthesiology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

- Suggest adding a flow chart as per the SPIRIT guidelines for clinical trial protocols.

Please clarify the rationale for combining the two drugs

CTRI registration would be mandatory before the trial is initiated after obtaining ethics approval

Decision: Minor revision

**Agenda No. 19**

**IEC code:** 2023-150-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** A Predictive Score for screening of Retinopathy of Prematurity in preterm infants in a tertiary care center

**PI:** Dr Abhishek Paul

**Department:** Neonatology

Primary reviewer (Technical): Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Is it a prospective or a retrospective study? If there is a prospective component, then the submission of a PID and ICF would be essential.

Decision: Minor revision

**Agenda No. 20**

**IEC code:** 2023-151-IP-132

**Type of submission:** Project Independent

**Title of project:** When less is more! The Outcomes and Surgical Nuances of Minimally Invasive Parotid Surgery for Pleomorphic Adenoma.

**PI:** Dr M. Ravi Shankar

**Department:** Neurosurgery

Primary reviewer (Technical): Dr. Arun Chaturvedi

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

It appears that your project has already been completed. The IEC considers projects before the work has been initiated. Completed work is not under the purview of the ethics committee for review.

**Agenda No. 21**

**IEC code:** 2023-152-IP-132

**Type of submission:** Project Independent

**Title of project:** Etiological spectrum of gastric outlet obstruction and outcome of endoscopic balloon dilatation of pyloric stenosis in children: a retrospective study

**PI:** Dr Ujjal Poddar

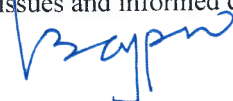
**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr. Uday C. Ghoshal

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Decision: Approved



**Lt Col Varun Bajpai VSM**  
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SGPGIMS, Lucknow

**Agenda No. 22**

**IEC code:** 2023-153-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** BODY COMPOSITION, NUTRITIONAL STATUS, FRAILTY AND QUALITY OF LIFE IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD) ON MAINTENANCE HEMODIALYSIS (MHD) AT A TERTIARY CARE CENTRE IN NORTH INDIA

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The period of the study is mentioned as November 2021 to May 2023. Is it prospective or retrospective? If retrospective, then a waiver of consent form would be required.

Decision: Minor revision

**Agenda No. 23**

**IEC code:** 2023-154-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Cirrhotic cardiomyopathy in children with chronic liver diseases: Correlation with severity of liver diseases and its effect on outcome

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. Decision: Approved

**Agenda No. 24**

**IEC code:** 2023-155-MCh-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Efficacy and Safety of Gravity Dependent and Hand Held Push Injection Methods of Contrast Cholangiography: Validation of A Pilot Study

**PI:** Dr Rajan Saxena

**Department:** Surgical Gastroenterology

Primary reviewer (Technical): Dr. Uday C. Ghoshal

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

Which patient shall get the Gravity Dependent and which shall get Hand Held Push Injection

Methods? How shall this be decided? If randomization would be done, then it would be a RCT which would have to be written as per SPIRIT guidelines.

How was the sample size decided upon? Since you have already done a pilot, you could use this data from the pilot for sample size calculation.

The IEC recommends that there should be a co-investigator from Radiodiagnosis since the procedure shall be done there.

Decision: Minor revision.



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**Agenda No. 25**

**IEC code:** 2023-156-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Epidemiology and outcomes of Extra-Pulmonary Fungal Infections among Renal Transplant Recipients

**PI:** Dr Anupama Kaul

**Department:** Nephrology

Primary reviewer PID and CF: Dr. Shagun Misra

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

Mention the estimated sample size.

Decision: Minor revision.

**Agenda No. 26**

**IEC code:** 2023-157-DM-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Nocardia infection in Kidney transplant recipients: A Tertiary Care Experience

**PI:** Dr Anupama Kaul

**Department:** Nephrology

Primary reviewer (Technical) Dr. Durga P. Misra

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

Decision: Approved

**Agenda No. 27**

**IEC code:** 2023-158-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** To study the feasibility of DARS optimized IMRT in pharyngeal cancers treated by neoadjuvant chemotherapy followed by concurrent CRT – A dosimetric exercise on CT data sets of already treated patients.

**PI:** Dr Punita Lal

**Department:** Radiotherapy

Primary reviewer PID and CF: Dr. Shagun Misra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The waiver of consent form is incomplete. Please provide a completed form.

The duration of the study is mentioned as April 2023 to 31st March 2025. Is it a prospective or a retrospective study? If prospective, then it would require a PID and ICF to be synthesized.

Decision: Minor revision

**Agenda No. 28**

**IEC code:** 2023-159-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Feasibility Of Taxane based Chemo-Radiotherapy in Ca Esophagus - A Prospective Observational study

**PI:** Dr Shaleen Kumar

**Department:** Radiotherapy

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review



**Lt Col Varun Bajpai VSM**  
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Scientific issues, ethical issues and informed consent documents were discussed. Decision: Approved

**Agenda No. 29**

**IEC code:** 2023-160-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Oligometastatic Breast Cancer: Analysis of practice patterns, outcomes and creation of prospective database

**PI:** Dr Shagun Misra

**Department:** Radiotherapy

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

PI has provided a waiver of consent form for the retrospective part of the study.

Decision: Approved

**Agenda No. 30**

**IEC code:** 2023-160-MD-132

**Type of submission:** Project DM/MCh/MD

**Title of project:** Measurement of Bone Loss after Initiation of Androgen Deprivation Therapy with Radiation Therapy or Surgery in patients with Prostate Cancer

**PI:** Dr Sushma Agrawal

**Department:** Radiotherapy

Primary reviewer PID and CF: Dr. Shagun Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The PID should mention the name and contact details of the PI and the current member secretary.

Decision: Minor revision

**In addition, the following projects which were approved in the Expedited Review Committee meeting on 27-04-2023 were ratified by the Full Board of the IEC.**

**Agenda No. 3**

**IEC code:** 2023-100-DM-EXP-52

**Type of submission:** Project DM/MCh/MD

**Title of project:** Serum BCMA in multiple myeloma and correlation with serum free light chain for response to therapy

**PI:** Dr Rajesh Kashyap

**Department:** Clinical Hematology

**Agenda No. 7**

**IEC code:** 2023-92-MCh-EXP-52

**Type of submission:** Project DM/MCh/MD

**Title of project:** "Recurrence of pain after drainage procedure for chronic pancreatitis-A retrospective and prospective study"



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**PI:** Dr Rajneesh Kumar Singh

**Department:** Surgical Gastroenterology

**Agenda No. 9**

**IEC code:** 2023-97-DM-EXP-52

**Type of submission:** Project DM/MCh/MD

**Title of project:** Role of peripheral blood neutrophil to lymphocyte ratio in severity and prognosis of hemorrhagic stroke

**PI:** Dr Ruchika Tandon

**Department:** Neurology

**Agenda No. 12**

**IEC code:** 2023-86-PhD-EXP-52

**Type of submission:** Project PhD

**Title of project:** Systematic and Comprehensive Re-analysis of Unsolved Genomic Sequencing Data in a Research Cohort of Mendelian Disorder

**PI:** Dr Moirangthem Amita

**Department:** Medical Genetics

**Agenda No. 16**

**IEC code:** 2023-96-IP-EXP-52

**Type of submission:** Project Independent

**Title of project:** Profile of children with cryptogenic multifocal ulcero-stenosing small bowel enteropathy (CMUSE)

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

**Agenda No. 18**

**IEC code:** 2023-102-EMP-EXP-52

**Type of submission:** Project Extramural

**Title of project:** Hepatic parenchymal extinction in extrahepatic portal venous obstruction

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

**Agenda No. 19**

**IEC code:** 2023-103-EMP-EXP-52

**Type of submission:** Project Extramural

**Title of project:** Utility of Contrast-Enhanced Mammography (CEM) in monitoring response to Neoadjuvant Chemotherapy in Breast Cancer Patients

**PI:** Dr Namita Mohindra

**Department:** Radiodiagnosis

**Agenda No. 20**

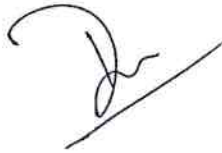
**IEC code:** 2023-104-EMP-EXP-52

**Type of submission:** Project Extramural

**Title of project:** Role of gut microbial dysbiosis, small intestinal bacterial overgrowth and immune activation in non-alcoholic fatty liver disease: A case-control study.

**PI:** Dr Gaurav Pandey

**Department:** Gastroenterology



(Dr. Durga P. Misra)  
Member Secretary,  
IEC, SGPGI



(Dr. M.K. Mitra)  
Chairman,  
IEC, SGPGI



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

MEETING NOTICE

131<sup>st</sup> Institutional Ethics Committee meeting is scheduled to be held on 12<sup>th</sup> May 2023 at 02:30 PM in a hybrid mode. The venue of this meeting is Committee Room of the Guest House, SGPGI Lucknow. Following members are requested to be present either physically or online.

Meeting ID and passcode will be communicated.

**Distribution : (A)**

1. Prof. M. K. Mitra, Retd. Professor, Dept. of Medicine, KGMU, Lucknow	Chairperson
2. Prof. S. P. Ambesh, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Ex-Officio Member
3. Dr. Gautam Palit, Former Chief Scientist and Head, Dept. of Pharmacology, CSIR, Lucknow	Member
4. Dr. Arun Chaturvedi, Retd. Head, Dept. of Oncology, KGMU, Lucknow	Member
5. Dr. Mala Kumar, Professor, Department of Pediatric, KGMU, Lucknow	Member
6. Dr. Uday C. Ghoshal, Prof. & Head, Department of Gastroenterology, SGPGI MS, Lucknow	Member
7. Dr. Vinita Agarwal, Professor, Department of Pathology, SGPGIMS, Lucknow	Member
8. Prof. Anand Vishwakarma, Professor of Law and Director Legal Cell, University of Lucknow	Member
9. Shri. Vijai Varma Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
10. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
11. Shri Sharad Jain, Shri Madhav Seva Ashram, Lucknow	Member
12. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
13. Mr. Anil Kumar Srivastava, Retd. Professor, Department of Sociology, University of Lucknow	Member
14. Dr. Shagun Misra, Additional Professor, Department of Radiotherapy, SGPGIMS, Lucknow	Alternate Member Secretary
15. Dr. Durga P. Misra, Associate Professor, Department of Clinical Immunology, SGPGIMS, Lucknow	Member Secretary

**(B)**

1. All Principal Investigators & Guides SGPGI
2. Director, SGPGI-for information please
3. Guest House Manager
4. JAO (Research)

**(Dr. Durga P. Misra)**  
Member Secretary IEC, SGPGI



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**A: Confirmation of minutes of previous meeting**

**Approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 130th IEC meeting held on 31.03.2023. All the members of IEC approved the minutes of the meeting.

**B. Review of New Proposals:**

**Agenda No. 1**

IEC code: 2023-104-EMP-131

Type of submission: Project Extramural

Title of project: Comparison of parenteral to oral split-dose methotrexate in terms of efficacy and intracellular methotrexate polyglutamate levels – A randomized controlled trial

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

To modify the title of the project

Comparison of parenteral to oral split-dose methotrexate in terms of efficacy and intracellular methotrexate polyglutamate levels in patients of Rheumatoid arthritis – A randomized controlled trial.

Please provide the PID in Hindi

Decision: Minor revision.

**Agenda No. 2**

IEC code: 2023-105-EMP-131

Type of submission: Project Extramural

Title of project: An analysis of the differential expression of Th17 lymphocytes and their novel subpopulations, Th17.1 and PD1+ Th17, in the context of autoimmune hepatitis and does they play a role in drug non-responsiveness

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

Hindi PID and English PID to be simplified. Title of the project should be simplified in the Consent form in Hindi.

Decision: Minor Revision

**Agenda No. 3**

IEC code: 2023-106-DM-131

Type of submission: Project DM/MCh/MD

Title of project: EUS-Guided Choledochoduodenostomy Vs ERCP FCSEMS For Preoperative Biliary Drainage In Malignant Biliary Obstruction: A Randomised Controlled Study

Comments:

Scientific issues, ethical issues and informed consent documents were discussed.

To specify in the PID whether both the procedures are standard of care and whether any additional costs will be borne by the patients. Additionally comment on the procedural costs, whether they are different between the arms. CTRI registration should be done after ethics approval.

Decision: Minor Revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Agenda No. 4**

IEC code: 2023-107-EMP-131

Type of submission: Project Extramural

Title of project: Development of patient derived organoid bio-bank as a resource for drug response studies and precision medicine applications in triple negative breast cancer  
Comment: Scientific issues, ethical issues and informed consent documents were discussed. There were no major ethical concerns.  
Decision: Approved

**Agenda No. 5**

IEC code: 2023-108-EMP-131

Type of submission: Project Extramural

Title of project: Prevalence and species identification of Leptospira infections among acute febrile illness cases and tracking of transmission sources using one health approach  
Comment: Scientific issues, ethical issues and informed consent documents were discussed.  
Hindi PID to be simplified and resubmitted  
Decision: Minor Revision

**Agenda No. 6**

IEC code: 2023-109-MD-131

Type of submission: Project DM/MCh/MD

Title of project: Bacterial profile of wound site infections and evaluation of risk factors for sepsis among road traffic accident (RTA) patients from Apex Trauma Centre, Northern India  
Comment: Scientific issues, ethical issues and informed consent documents were discussed.  
Simplify and resubmit Hindi and English PID.  
Decision: Minor Revision

Subject: Project for review

**Agenda No. 7**

IEC code: 2023-110-DM-131

Type of submission: Project DM/MCh/MD

Title of project: Clinical Characteristics, Diagnosis and Management of the Patients of Idiopathic Intracranial Hypertension  
Comments:  
Scientific issues, ethical issues and informed consent documents were discussed.  
Primary objective is not reflected in the title.  
Modify the title to indicate the assessment of the value of surgery in acetazolamide refractory cases.  
Modify the Hindi and English PID accordingly. To mention in the PID regarding any additional costs to the patient as part of participation in the study.  
Decision: Major Revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

Agenda No. 8

IEC code: 2023-111-MD-131

Type of submission: Project DM/MCh/MD

Title of project: Comparison of CT and Robot assisted CT guided celiac plexus neurolysis (CPN) in cases of upper abdominal malignancy: Prospective Randomised comparative parallel trial  
Comment: Scientific issues, ethical issues and informed consent documents were discussed.  
Modify Hindi PID to clarify about side effects. CTRI registration after ethics approval is mandatory.  
Decision: Minor revision.

Subject: Project for review

Agenda No. 9

IEC code: 2023-112-IP-131

Type of submission: Project Independent

Title of project: A randomized crossover study to compare the performance characteristics of two sequential sizes of I-gel in anaesthetized paralyzed patients

Comments: Scientific issues, ethical issues and informed consent documents were discussed.  
Hindi and English PID to be modified to remove "Kindly refer to..." and simplified (such as simple language for endotracheal intubation). Mention in the PID that there will be no financial burden on the patient. CTRI registration after ethics approval is mandatory.

Decision: Minor revision.

Subject: Project for review

Agenda No. 10

IEC code: 2023-113-DM-131

Type of submission: Project DM/MCh/MD

Title of project: Effect of Diuretics, Midodrine & beta blockers in Hemodynamics of Chronic Liver Disease with ascites: A Pilot Study

Comments:  
Scientific issues, ethical issues and informed consent documents were discussed.  
Hindi and English PID to be simplified and resubmitted. PID in certain instances uses past tense, please use the future tense. PID to mention about additional tests and added costs to the patient by participating in the study. PI to clarify whether 3 monthly Ultrasound and blood tests are standard of care.

Minor Revision

Agenda No. 11

IEC code: 2023-114-IP-131

Type of submission: Project Independent

Title of project: Intravesical Dexmedetomidine for prevention of post-operative catheter related bladder dysfunction in renal transplant recipients- a prospective randomized double-blind, placebo-controlled study.

Comments:  
Scientific issues, ethical issues and informed consent documents were discussed.  
Title: is it "discomfort" or "dysfunction"? Please clarify.  
Modify PID, Question 6: Study over in 24hrs and Question 10; document side effects of intravesical administration of the drug. CTRI registration after ethics approval is mandatory.  
Decision: Minor revision.

Subject: Project for review



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 12**

IEC code: 2023-115-PhD-131

Type of submission: Project PhD

Title of project: Understanding arterial wall fibrosis in Takayasu arteritis: role of macrophages in driving the activation of aortic adventitial fibroblasts and exploration of therapeutic targets

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

Modify PID for controls

Decision: Minor revision.

Subject: Project for review

**Agenda No. 13**

IEC code: 2023-116-IMP-131

Type of submission: Project Intramural

Title of project: Understanding arterial wall fibrosis in Takayasu arteritis: Effect of sera from TAK on fibrotic pathways in aortic adventitial fibroblasts, and its potential therapeutic modulation.

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

Modify PID for controls

Decision: Minor revision.

**Agenda No. 14**

IEC code: 2023-117-EMP-131

Type of submission: Project Extramural

Title of project: Circulating monocyte/ macrophage phenotype, gene expression profile, and in vivo arterial wall macrophage activity using SST2 PET as markers of Takayasu arteritis disease activity

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

Modify PID for controls

Decision: Minor revision.

**Agenda No. 15**

IEC code: 2023-118-EMP-131

Type of submission: Project Extramural

Title of project: Role of Proteomic Biomarkers in Early Fetal Growth Restriction

Scientific issues, ethical issues and informed consent documents were discussed.

Please clarify whether the third objective is to be carried out on blood or on placenta.

Please clarify the number of patients and controls.

Please present the study in the form of a flowchart.

Decision: Minor revision.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

Agenda No. 16

IEC code: 2023-119-PhD-131

Type of submission: Project PhD

Title of project: Investigating the RPTOR gene protein expression as a function of epigenetic regulation in Gastric Adenocarcinoma

Comment: Provide waiver of consent form for patients enrolled from stored samples.  
The PID should correctly mention the details of member secretary.

Subject: Project for review

Agenda No. 17

IEC code: 2023-120-SRF-131

Type of submission: Project SRF/JRF

Title of project: Evaluating CD4+ T lymphocyte-macrophage cross-talk in the pathogenesis of arterial wall fibrosis in Takayasu arteritis and its therapeutic modulation.

Comments: Scientific issues, ethical issues and informed consent documents were discussed.  
Modify PID for controls  
Decision: Minor revision.

Subject: Project for review

Agenda No. 18

IEC code: 2023-121-EMP-131

Type of submission: Project Extramural

Title of project: Role of Urinary Tissue Inhibitor of Metalloproteinase-2 and Insulin-Like Growth Factor Binding Protein- 7 in early prediction of Acute Kidney Injury in critically ill neonates.

Comments:  
Scientific issues, ethical issues and informed consent documents were discussed.  
Modify language in the PID as "your child" is being invited to take part in the study. Modify responses to question 7 and 15 in the PID.

Decision: Minor revision.

Subject: Project for review

Agenda No. 19

IEC code: 2023-122-MD-131

Type of submission: Project DM/MCh/MD

Title of project: Effect of single bolus dose of ketodex and ketofol on emergence agitation in patients undergoing transsphenoidal pituitary surgery: A prospective double blinded randomized clinical trial

Comments: Scientific issues, ethical issues and informed consent documents were discussed.  
Minor translational errors in Hindi PID need to be rectified and resubmitted.  
Decision: Minor revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 20**

IEC code: 2023-123-DT-131

Type of submission: Project Drug/device trials

Title of project: A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Active Controlled Study to Evaluate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, Versus Apixaban in Participants with Atrial Fibrillation  
Scientific issues, ethical issues and informed consent documents were discussed.  
Comments of legal reviewer:

- 1- The Sponsor, Janssen Research and Development, LLC, USA, is shown as a party but it is not a signatory to the CTA. Instead Iqvia RDS, India, Pvt. Ltd., is shown as an authorized signatory on behalf of the Sponsor. This may create problems if there is any breach of the provisions of the CTA by either the Sponsor or The Iqvia, its authorized representative. Besides, it transpires that a separate agreement has been reached between the Sponsor and the Iqvia RDS as CRO to act on behalf of Sponsor as its authorized representative but that agreement is not on record to assess its impact on the instt. CTA and the consequential discharge of the responsibilities and liabilities of the Sponsor. Hence let the copy of that separate agreement between the Sponsor and its representative Iqvia RDS be filed for making a proper assessment of its impact on the CTA.
- 2- In Cl.14 of the CTA, it is provided that the jurisdiction of the courts will be at Mumbai in case of any unsettled dispute arising out of the provisions of the CTA. In fact as the study is to be conducted in Lucknow, hence the jurisdiction of the courts should be at Lucknow instead of Mumbai.
- 3- In the Insurance policy, the insured is shown as Johnson and Johnson Pvt Ltd, whereas the name of the Sponsor is Janssen Research and Development LLC. Why is it so, has got to be explained. No other issue is discernible.

Decision: Minor revision

Subject: Project for review

**Agenda No. 21**

IEC code: 2023-124-DM-131

Type of submission: Project DM/MCh/MD

Title of project: Norepinephrine versus epinephrine for fluid refractory septic shock in neonates: A Randomized Controlled Trial (Pilot Study)

**Comments:**

Scientific issues, ethical issues and informed consent documents were discussed. Title should include "reversal of fluid refractory septic shock within an hour".

Since participants up to 3 months are included, title should include neonates and infants.

Blinding might be feasible: PI may consider incorporating this in the study design.

PID should include PI contact details (not student's details) and also details of member secretary, ethics committee.

Modify language in the PID as "your child" is being invited to take part in the study. Modify responses to question 7 and 15 in the PID

Decision: Minor revision

Subject: Project for review

**Agenda No. 22**

IEC code: 2023-125-MD-131

Type of submission: Project DM/MCh/MD

Title of project:



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SCPGIMS, Lucknow

**EVALUATION OF PREOPERATIVE ACUPRESSURE ON ACUPOINTS ON PROPOFOL INDUCTION DOSE: A SINGLE BLIND, RANDOMISED CONTROLLED STUDY**

**Comments:** Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.

**Agenda No. 23**

**IEC code: 2023-126-EMP-131**

**Type of submission: Project Extramural**

**Title of project: Role of Extracellular Vesicles in the Susceptibility and Recurrence of Urinary Tract Infections in Children: A Prospective Cohort Study**

**Comments:**

Scientific issues, ethical issues and informed consent documents were discussed.

Title should include "urinary" ECVs and "diagnosis" rather than "susceptibility".

Hindi PID requires modification – Hindi PID title should be the title in Hindi rather than writing the English title in Hindi.

**Decision: Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 24**

**IEC code:** 2023-127-EMP-131

**Type of submission:** Project Extramural

**Title of project:** Factors associated with sudden deaths among adults aged 18–45 years, India: Multicentric matched case-control study

**PI:** Dr Alka Verma

**Department:** Emergency Medicine

Primary reviewer (Technical): Dr Vinita

Agrawal Primary reviewer PID and CF: Ms.

Shalini Mathur

**Subject:** Project for review

Comments: Scientific issues, ethical issues and informed consent documents were discussed. ICMR approved study. There were no major ethical concerns.

Approved by ethics

**Agenda No. 50**

**IEC code:** 2023-128-DM-131

**Type of submission:** Project DM/MCh/MD

**Title of project:** Colon transit study for assessment of chronic constipation and therapy directed against fecal evacuation disorder by biofeedback with or without transcutaneous electrical stimulation of posterior tibial nerve

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Dr A K

Srivastava

**Subject:** Project for review

Comments: Scientific issues, ethical issues and informed consent documents were discussed. There were no major ethical concerns. Approved.

**Agenda No. 51**

**IEC code:** 2023-94-IP-131

**Type of submission:** Project Independent

**Title of project:** Improving Patient Care and Operational Efficiency with Shared Medical Appointment: Evidence from Randomized Control Trial in Pediatric Urology

**PI:** Dr Priyank yadav

**Department:** Urology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Dr. Manuka

Khanna

**Subject:** Project for review

Comments:

Scientific issues, ethical issues and informed consent documents were discussed.

Privacy and confidentiality issues were discussed and the ethics committee suggested change in study design as shared decision making approach violates confidentiality and privacy of the participants. The PI might like to redesign the submit and resubmit as a new proposal.

**D. Notification for Amendments/Addendum:**

**Agenda No. 25**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**IEC code:** 2019-110-DM-109

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Comparison of efficacy and safety of Low (20 mg) vs High (40mg) dose oral Prednisolone in Complex Regional Pain Syndrome

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Amendment report (Reporting date 01-05-2023)

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Agenda No. 26**

**IEC code:** 2018-1-OTHERS-EXP

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Indian Registry in Ischemic Stroke with Tenecteplase (TNK tPA)

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:**

Study related Documents(1. DCGI Approval letter, Version not applicable, 2. Version Dated 04 Nov 2022, Amend Active PMS Study Protocol Version 2.1, Version Dated 29 Oct 2022, 3. Summary of Changes in Protocol Version not applicable, Version dated 03 Nov 2022, 4. ICF-English Hindi and local language, Version dated 31 Oct 2022, 5. ICF Translation Certificates: English -Local Language-English translation. Version 2.1, Version Dated 31 Oct 2022 and 6. ICF back translation from English -Local Language-English t Version 2.1, Version Dated 31 Oct 2022).

Since there is a change in participant PID, DCGI should be notified.

**Noted and approved.**

**E. Notification for protocol deviation:**

**Agenda No. 27**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Protocol deviation (Subject no 41050100and 41050266).

**Noted and approved.**

**E. General Notification:**

**Agenda No. 29**

**IEC code:** 2020-196-DT-115

**Type of submission:** General Notification

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Noted and approved.**

**Subject:** General Notification (Updated CIOMS from dated 22.03.2023 for the Subject 406-009-0002).

**Agenda No. 30**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Subject:** Investigator Undertaking dated 18 Feb 2023.

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 31**

**IEC code: 2022-179-DT-129**

**Type of submission:** General Notification

**Title of project:** A Prospective, openabled, Multicenter, Observational, Registry of ISAR SUMMIT IN CAD Patients undergoing PCI in real world indian population (TRANSEVER REGISTRY).

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Noted and approved.**

**Subject:** Notification of signed CTA copy.

**Agenda No. 32**

**IEC code: 2022-72-DT-128**

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Noted and approved.**

**Subject:** Study related documents (1. Brief Fatigue Inventory (BFI) Hindi - Translation certificate dated 17 sep 2009, 2. Patients facing Materials provided to Study participants for 24 Hr urine collection English version 3.0 dated 02 Aug 2022, 3. 24-hours Urine collection Instruction and Diary \_3.0\_27 Jan2022; Patient ID and Emergency Card \_1.0\_23Nov2021; Spot Urine Collection Instructions and Diary \_3.0\_37 Jan 2022 -Hindi-Translation certificate dated 24 Feb 2022, 4. Certificate of Insurance CT 21044241A-417-20100007 upadted dated 04 Jul 2022).

**Agenda No. 33**

**IEC code: 2022-72-DT-128**

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Noted and approved.**

**Subject:** Memorandum to notify the error in Country and Site level ICF for IEC Notification.

**Agenda No. 34**

**IEC code: 2022-72-DT-128**

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Study related documents review and approval V4.1.1 dated 13 Apr 2022 etc.

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

Since there is a change in participants and additionally pharmacokinetic/ pharmacodynamic studies shall be carried out, DCGI should be informed.

Noted and approved.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 35**

**IEC code:** 2017-47-DT-96

**Type of submission:** General Notification

**Title of project:** Investigation of Rheumatic AF Treatment Using vitamin K antagonists, rivaroxaban or aspirin Studies. (INVICTUS)

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** IEC notification of DSMB letter dated 01 February 2022 and study Site Close out

**Noted and approved.**

**Agenda No. 36**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Investigator Brochure Ed: 6 (reporting date 12.04.2023).

**Noted and approved.**

**Agenda No. 37**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Name change in central Laboratory (Labcorp Development (Asia) Pte. Ltd.)

**Noted and approved.**

**Agenda No. 38**

**IEC code:** 2020-196-DT-115


**Type of submission:** General Notification

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** DCGI Approval Letter on Protocol Amendment 4 dated 25 April 2023

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

Noted and approved.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 39**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** DSMD form (1. Date of Review meeting: 8 Jul 2021, 2. Date of Review meeting:9 Sep 2021, 3. Date of Reviewmeeting: 28 Oct 2021, 4. Date of Review meeting: 15 Mar 2022 and 5. Date of Review meeting: 6 Sep 2022)

**Noted and approved.**

**Agenda No. 40**

**IEC code:** 2020-329-DT-117

**Type of submission:** General Notification

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Investigator Undertaking dated 24 Apr 2023

**Noted and approved.**

**Agenda No. 41**

**IEC code:** 2021-346-DT-124

**Type of submission:** General Notification

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Diseasesubcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** General Notification (EXPANDED (Final) e CRF Version 1 Dated 15 Dec 2021)

**Noted and approved.**

**G. SAE:**

**Agenda No. 28**

**IEC code:** 2020-286-DT-116

**Type of submission:** SAE reports-Outside-Log

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from dated 01 Nov 2022 to 31 Jan 2023 ( Follow up 10 and Patient ID 1703-002)

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
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SGPGIMS, Lucknow

**Agenda No. 49**

**IEC code:** 2017-173-IMP-99(B)

**Type of submission:** Study Close out Notification

**Title of project:** To study the phenotypic spectrum of a cohort of patients with Parry Romberg syndrome and to identify the copy –number variations by cytogenetic microarray.

**PI:** Dr Deepti Saxena

**Department:** Medical Genetics

**Subject:** Study Completion report (Date of termination: 31-12-2021)

**Noted and approved.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 42**

**IEC code:** 2019-188-IMP-113

**Type of submission:** Final/Annual/Progress reports

**Title of project:** EVALUATION OF EOSINOPHILIC INFLAMMATION IN PATIENTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

**PI:** Dr Mansi Gupta

**Department:** Pulmonary Medicine

**Subject:** Annual Progress report dated 06-04-2023

**Noted and approved.**

**Agenda No. 43**

**IEC code:** 2020-196-DT-115

**Type of submission:** Final/Annual/Progress reports

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Annual report dated 29-03-2023

**Noted and approved.**

**Agenda No. 44**

**IEC code:** 2020-33-IMP-114

**Type of submission:** Final/Annual/Progress reports

**Title of project:** Effects of catecholamine excess on glucose and fat metabolism in Pheochromocytoma & Paraganglioma patients and their reversal following surgical cure: A Prospective Cohort Study

**PI:** Dr Gaurav Agrawal

**Department:** Endocrine Surgery

**Subject:** Annual report dated 15-12-2022

**Noted and approved.**



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**Agenda No. 45**

**IEC code:** 2020-19-EMP-114

**Type of submission:** Study Close out Notification

**Title of project:** An open label randomized controlled trial to compare the serological response to 1.0 ml versus 2.0 ml intramuscular four doses schedule of hepatitis B vaccine in pre-dialysis chronic kidney disease patients with eGFR below 60 ml/min

**PI:** Dr Amit Goel

**Department:** Hepatology

**Subject:** Premature termination report dated 23rd April 2023

**Noted and approved.**

**Agenda No. 46**

**IEC code:** 2022-25-DT-125

**Type of submission:** Study Close out Notification

**Title of project:** A streamlined, multicentre, randomized, parallel group, double-blind placebo-controlled superiority trial to evaluate the effect of EMPAgliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Premature termination report (Date of termination 2 Feb 2023)

**Noted and approved.**

**Agenda No. 47**

**IEC code:** 2019-46-EMP-108

**Type of submission:** Study Close out Notification

**Title of project:** Outcome in adulthood of children with Enthesitis related arthritis (ERA) category of juvenile idiopathic arthritis (JIA) and its predictors

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Study Completion report ( Date of termination May 2022)

**Noted and approved.**

**Agenda No. 48**

**IEC code:** 2020-312-IMP-EXP-33

**Type of submission:** Study Close out Notification

**Title of project:** Micro-RNA mediated regulation of Th17 and Treg cells in Aplastic anemia and their correlation with Immunosuppressive therapy.

**PI:** Dr Ruchi Gupta

**Department:** Hematology

**Subject:** Study completion report ( Date of Termination: 24-12-2022) **Noted and approved.**



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**Table Agenda:**

**Agenda No. 52**

**IEC code:** 2023-129-DT-131

**Type of submission:** Project Drug Trial

**Title of project:** A Randomized, Controlled, Open-label, Multicenter, Inferentially Seamless Phase 2/3 Study of Ibrutinib in Combination With Rituximab Versus Physician's Choice of Lenalidomide Plus Rituximab or Bortezomib Plus Rituximab in Participants with Relapsed or Refractory Mantle Cell Lymphoma

**PI:** Dr Sanjeev

**Department:** Clinical Hematology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer Legal: Judge Vijai Verma

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Project was withdrawn by the PI before the meeting as the trial was terminated by the sponsor.

**Agenda No. 53**

**IEC code:** 2023-130-EMP-131

**Type of submission:** Project Intramural

**Title of project:** Exploratory Imaging Study to Assess the Safety, Tolerability and Biodistribution of the Novel Glypican-3 (GPC3) Targeted Radiotracers RAYZ-8009 and RAYZ-8030 in Patients with Locally Advanced or Metastatic Hepatocellular Carcinoma (HCC) Undergoing Restaging

**PI:** Dr S Gambhir

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Shagun Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Comments: Scientific issues, ethical issues and informed consent documents were discussed.

First in human study. To submit animal safety data and approval from recommended regulatory bodies

Decision: Major revision.

**Agenda No. 54**

**IEC code:** 2023-131-IMP-131

**Type of submission:** Project Intramural

**Title of project:** DNA methylation changes in intron 1 of RPTOR gene in patients with Gastric Adenocarcinoma: a pilot study

**PI:** Dr Raghavendra L

**Department:** Pathology

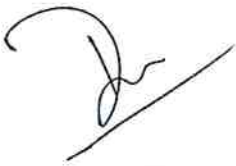
Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Comments: Scientific issues, ethical issues and informed consent documents were discussed. There were no major ethical concerns.

Approved.



(Dr. Durga P. Misra)  
Member Secretary,  
IEC, SGPGI



(Dr. M.K. Mitra)  
Chairman,  
IEC, SGPGI



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SGPGIMS, Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 130<sup>th</sup> Institutional Ethics Committee** meeting held on 31st March 2023, at 2:30 PM, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

**Present:**

1. Prof. M. K. Mitra, Retd. Professor, Dept. of Medicine, KGMU, Lucknow	Chairperson
2. Prof. S. P. Ambesh, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Ex-Officio Member
3. Dr. Gautam Palit, Former Chief Scientist and Head, Dept. of Pharmacology, CSIR, Lucknow	Member
4. Dr. Arun Chaturvedi, Retd. Head, Dept. of Oncology, KGMU, Lucknow	Member
5. Dr. Mala Kumar, Professor, Department of Pediatric, KGMU, Lucknow	Member
6. Dr. Uday C. Ghoshal, Prof. & Head, Department of Gastroenterology, SGPGI MS, Lucknow	Member
7. Dr. Vinita Agarwal, Professor, Department of Pathology, SGPGIMS, Lucknow	Member
8. Prof. Anand Vishwakarma, Professor of Law and Director Legal Cell, University of Lucknow	Member
9. Shri. Vijai Varma Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
10. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
11. Shri Sharad Jain, Shri Madhav Seva Ashram, Lucknow	Member
12. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
13. Mr. Anil Kumar Srivastava, Retd. Professor, Department of Sociology, University of Lucknow	Member
14. Dr. Shagun Mishra, Additional Professor, Department of Radiotherapy, SGPGIMS, Lucknow	Alternate Member Secretary
15. Dr. Durga P. Misra, Associate Professor, Department of Clinical Immunology, SGPGIMS, Lucknow	Member Secretary

**Determination of quorum:** quorum was complete: 13 members present, with 9 non-institutional members.

**A: General discussions and confirmation of Minutes:**

**Approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 129th IEC meeting held on 15.12.2022. All the members of IEC approved the minutes of the meeting.



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**B. Review of New Proposals:**

**Agenda No. 1**

**IEC code:** 2023-37-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Evaluation of Occult Renal Dysfunction using Functional Magnetic Resonance Imaging in Patients with Cirrhosis

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

In ICF the word 'subject' is wrongly translated as विषय. It should be प्रतिभागी.

Please separate PID from ICF.

Clarify that MRI shall not be charged to the patient.

**Decision: Minor revision**

**Agenda No. 2**

**IEC code:** 2023-40-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Pituitary function after recovery from septic shock among ICU survivors: A prospective observational study

**PI:** Dr Subhash Yadav

**Department:** Endocrinology

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Correct specimen collection on page 1**

pg 27 'Patient information document' title itself be translated in hindi. This will bring more clarity.

**Decision: Minor revision**



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**Agenda No. 3**

**IEC code:** 2023-43-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Role of Maternal Soluble Neuropilin-1 and Placental Neuropilin-1 in fetal growth restriction

**PI:** Dr Neeta Singh  
Health

**Department:** Maternal & Reprod.

Primary reviewer (Technical): Dr. Mala Kumar

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

In PID - The word subject is wrongly translated as विषय.

PID should include current member secretary contact and details.

**Decision: Minor revision**

**Agenda No. 4**

**IEC code:** 2023-45-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Effect of oral bicarbonate therapy on disease progression, inflammatory markers and urinary klotho in Chronic Kidney Disease patients (Stage 3-4) : A prospective observational cohort study

**PI:** Dr Anupama Kaul

**Department:** Nephrology

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please simplify the Hindi PID.

Please modify the PID to include the details of the member secretary.

Please clarify if the study is a parallel group observational study or a RCT. If it is a RCT, then the PI should follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval.

**Decision: Minor revision**



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SGPGIMS, Lucknow



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SGPGIMS, Lucknow



**Agenda No. 5**

**IEC code:** 2023-46-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Benefit of intermittently scanned Continuous Glucose Monitoring (isCGM) in Reducing Hypoglycemia among Older Adults with Type 2 Diabetes Mellitus on Insulin

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please modify the PID to include the details of the member secretary.

Please clarify if the study is a parallel group observational study or a RCT. If it is a RCT, then the PI should follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval.

**Decision: Minor revision**

**Agenda No. 6**

**IEC code:** 2023-47-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Bone Health Assessment in patients of Prolactinoma

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

PID should include details of current member secretary.

**Decision: Minor revision**



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SGPGIMS, Lucknow

**Agenda No. 7**

**IEC code:** 2023-49-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Investigation of autophagy regulation as a potential therapeutic approach in glioblastoma

**PI:** Dr L K Sharma

**Department:** Molecular Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

PID should include details of current member secretary.

**Decision: Minor revision**

**Agenda No. 8**

**IEC code:** 2023-53-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Evaluation of glycemic and metabolic control by continuous glucose monitoring in children with Glycogen Storage Disease

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

In PID - The word subject is wrongly translated as विषय.

Consider including a control group if possible.

**Decision: Minor revision**



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**Agenda No. 9**

**IEC code:** 2023-57-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Association of Gut microbiota with the appearance of non-HLA antibodies and graft outcome in renal allograft recipients

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Clarify that the tests are to be done at no cost to the patient.

**Decision: Minor revision**

**Agenda No. 10**

**IEC code:** 2023-60-IMP-130

**Type of submission:** Project Intramural

**Title of project:** To study the role of insulin resistance and decreased beta-cell function in ESRD for the prediction of new onset diabetes after transplantation (NODAT)

**PI:** Dr Anupama Kaul

**Department:** Nephrology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please modify the PID to include the details of the member secretary.

Please simplify the language of the PID.

Clarify time points at which samples shall be taken and the frequency of samples.

What is the impact of detecting NODAT? Do patients continue in the study or do they drop out?

**Decision: Minor revision**

  
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SGPGIMS, Lucknow



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**Agenda No. 11**

**IEC code:** 2023-66-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Comparison of measured Glomerular Filtrate Rate with various Glomerular Filtrate Rate estimation equations in patients with posterior urethral valve

**PI:** Dr Manish Ora

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 12**

**IEC code:** 2023-69-IMP-130

**Type of submission:** Project Intramural

**Title of project:** Correlation of arterial concentrations of Dexmedetomidine with severity of Catheter Related Bladder Discomfort in male patients undergoing Percutaneous Nephrolithotomy after receiving Intravesical Dexmedetomidine.

**PI:** Dr Divya Srivastava

**Department:** Anaesthesiology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The project was reviewed and suggests that the subjects in the study will be randomly assigned to two study groups. The committee suggested to either proceed with a parallel group observational study or follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title.. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval

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**Decision: Minor revision**



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**Agenda No. 13**

**IEC code:** 2023-68-IMP-130

**Type of submission:** Project Intramural

**Title of project:** To study the impact of voluntary kidney donation on acid base balance

**PI:** Dr Manas Ranjan Behera

**Department:** Nephrology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 14**

**IEC code:** 2023-73-IMP-130

**Type of submission:** Project Intramural

**Title of project:** A pilot study of maintenance nivolumab after consolidation chemoradiation in partial responders to first line chemotherapy

**PI:** Dr Sushma Agrawal

**Department:** Radiotherapy

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The main purpose of the ethical committee is to take care of the interests of the patient. The primary reviewers Dr Gautam Palit and Dr Arun Chaturvedi (who is an oncosurgeon), the lay members and other members of the ethics committee felt that for a drug that was of doubtful benefit it might not be right for a patient to pay for it. The committee was of the opinion that PI should seek funding for the drug being administered from companies that market the drug for this purpose or any other extramural funding source.

If this is a new drug not recommended by the DCGI for this indication, then the PI should also seek DCGI approval and insurance cover for this pilot trial as required by regulatory authorities.

CTRI registration would also be required for this study after obtaining ethics approval.

**Decision: Major revision**

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SGPGIMS, Lucknow





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**Agenda No. 15**

**IEC code:** 2023-38-EMP-130

**Type of submission:** Project Extramural

**Title of project:** A prospective study to explore the genotypic and phenotypic landscape of pediatric epilepsies in north Indian Population

**PI:** Dr Deepti Saxena

**Department:** Medical Genetics

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 16**

**IEC code:** 2023-39-EMP-130

**Type of submission:** Project Extramural

**Title of project:** An Indo-German approach to identify universal and specific molecular targets in breast cancer prevention: Impact of environmental endocrine disruptors, diet and lifestyle on sex hormone levels and cellular consequences thereof in human breast tissues

**PI:** Dr Gaurav Agrawal

**Department:** Endocrine Surgery

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Dr. Manuka Khanna

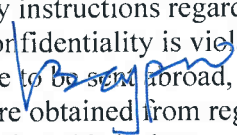
**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
Title change is approved to: Impact of environmental endocrine disruptors, diet and lifestyle on sex hormone levels and consequences thereof in breast tissues of Indian and German Women**

PID should be modified

1. Point 6 mentions only instructions regarding how to prepare the PID. Please modify.
2. Point number 16 : Confidentiality is violated. Please modify.

If any tissue samples are to be sent abroad, then it is the responsibility of PI to ensure that appropriate approvals are obtained from regulatory authorities and material transfer agreement is in place before this is done.

  
**Dr. Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

PI should ensure that all the participating centers have appropriate ethical clearance.

**Decision: Minor revision**

**Agenda No. 17**

**IEC code: 2023-51-DM-130**

**Type of submission:** Project Extramural

**Title of project:** Molecular scrutiny of Growth-disrupting sequence variations in epigenes and their methylation signatures in Overgrowth syndromes

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Submit Parents/LAR consent and PID form in Hindi.

Submit child assent in Hindi and English.

The contact person in PID should include PI & Member Secretary's name from SGPGIMS.

Clarify the source of funding, ethics clearance from other centres and whether these tests are going to be done at SGPGIMS laboratory or outside.

**Decision: Minor revision**

**Agenda No. 18**

**IEC code: 2023-52-EMP-130**

**Type of submission:** Project Extramural

**Title of project:** A prospective, randomized, two-arm, parallel, placebo-controlled, multicenter, superiority, phase II clinical trial to evaluate the immunogenicity and safety of Recombinant Hepatitis E Vaccine (Adsorbed) of M/s. Zydus Lifesciences Limited in healthy subjects

**PI:** Dr Amit Goel

**Department:** Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review



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Executive Registrar  
SGPGIMS, Lucknow

**Scientific issues, ethical issues and informed consent documents were discussed.**  
Since the study involves children also, please ensure that child assent form and PID for children is also provided.

Please revise the Department to Department of Hepatology and provide DRC from this department for the same.  
PI should ensure ethics approval from all centers for the project.

Comments of legal reviewer

1-In CTA in cl.12.2 pertaining to the Adverse Events, it transpires that the Sponsor has the required Insurance policy to cover adverse events and injury to the Study Subjects but it nowhere mentions that in case of adverse events appropriate treatment is to be provided in the Institute at the cost of the Sponsor, hence that should be specifically mentioned in this provision itself.  
2- There is no provision for the redressal of the dispute in the CTA, hence a provision to that effect be added and in case the dispute is not resolved, then the matter may be taken to the courts at Lucknow instead of Ahmedabad as the trial is to be conducted at Lucknow.  
3-From the Insurance certificate it transpires that the the Insurance policy has expired on 19.03.2023, hence the Insurance policy needs to be extended till the completion of the Study.

Decision: Minor revision

**Agenda No. 19**

**IEC code: 2023-56-EMP-130**

**Type of submission:** Project Extramural

**Title of project:** Evaluation of accelerated ageing in diabetes through investigation of biomarkers of ageing in human diabetic cohort and animal model

**PI:** Dr L K Sharma

**Department:** Molecular Medicine

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**  
PI should seek animal ethics committee clearance before proceeding for animal studies.  
Source of funding to be clarified.  
PID should reflect details of current member secretary.

Decision: Minor revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 20**

**IEC code: 2023-58-EMP-130**

**Type of submission:** Project Extramural

**Title of project:** Driving Co-Development of mHTT lowering Drugs and complementary Blood-based Diagnostics to Combat Huntington disease related Mental Illness

**PI:** Dr Anshika Srivastava

**Department:** Medical Genetics

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Comments:**

1. Please rewrite the PID(English and Hindi) for patients, controls, and children so that it is in simple understandable language.
2. Please provide a child assent form for older children.
3. Hindi PIDs are not visible in the uploaded document. Please provide.
4. Submit the consent of head of department document.
5. PID should mention member secretary details.

Decision: Minor revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 21**

**IEC code:** 2023-59-EMP-130

**Type of submission:** Project Extramural

**Title of project:** INDIAn asymptomatic gallStones: natural course and their predictors (INDIASTONE STUDY)

**PI:** Dr Anu Behari

**Department:** Surgical Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Hindi PID is missing. Please provide it.

PI should ensure ethics approval from all centers for the project.

**Decision: Minor revision**

**Agenda No. 22**

**IEC code:** 2023-63-EMP-130

**Type of submission:** Project Extramural

**Title of project:** Understanding arterial wall fibrosis in Takayasu arteritis: role of circulating T helper lymphocytes in driving the activation of TGF-beta mediated pathways in aortic adventitial fibroblasts and its potential for therapeutic modulation

**PI:** Dr Durga Prasanna Misra

**Department:** Clinical Immunology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 23**

**IEC code:** 2023-71-EMP-130

**Type of submission:** Project Extramural

**Title of project:** Mycophenolate mofetil and prednisolone versus prednisolone alone in chronic hypersensitivity pneumonitis: a randomized controlled trial

**PI:** Dr Mansi Gupta

**Department:** Pulmonary Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 24**

**IEC code:** 2023-81-EMP-130

**Type of submission:** Project Extramural

**Title of project:** Incidence, determinants and development of risk scoring system of long-term complications in Covid-19 recovered patients: A cohort study

**PI:** Dr Prabhaker Mishra

**Department:** Biostatistics

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.  
It is noted that some patients might not be able to provide written informed consent as they are contacted through phone. Such patients should provide verbal consent duly recorded (audio or audiovisual) and witnessed by a third person who is not a study participant.

**Decision: Approved**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 25**

**IEC code:** 2023-10-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Autoimmune rheumatic diseases in families of patients with juvenile arthritis especially children with ERA

**PI:** Dr Amita Aggarwal

**Department:** Clinical

Immunology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 26**

**IEC code:** 2023-2-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Bronchosopic Assessment of Swallowing Dysfunction in Critically Ill Patients: A Prospective Observational Study

**PI:** Dr Banani Poddar

**Department:** Critical Care Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

PID should reflect details of current member secretary.

**Decision: Minor revision**

**Agenda No. 27**

**IEC code:** 2023-30-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** DIAGNOSTIC ACCURACY OF FVD/FAD RATIO AND IVC FOR PREDICTION OF VOLUME STATUS IN CRITICALLY ILL PATIENTS

**PI:** Dr Afzal Azim

**Department:** Critical Care Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Agenda No. 28**

**IEC code:** 2023-41-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Feasibility and acceptability of using Intermittently Scanned Continuous Glucose Monitoring System Freestyle Libre (FSL) in patients under 18 years age with type 1 diabetes mellitus visiting a tertiary care hospital in North India

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

PID should reflect details of current member secretary.

Appropriate PID and ICF for child assent for older children should be provided.

**Decision: Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 29**

**IEC code:** 2023-44-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Prevalence, clinical characteristics, and outcomes of Chronic critical illness:  
A retrospective study

**PI:** Dr Shreyas Hanumantrao  
Gutte

**Department:** Critical Care Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and waiver of consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 30**

**IEC code:** 2023-51-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Cytomegalovirus reactivation in acute necrotizing pancreatitis

**PI:** Dr Mohan Gurjar

**Department:** Microbiology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 31**

**IEC code:** 2023-55-MD-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** "ASSESSMENT OF HAEMOSTATIC ALTERATIONS IN PATIENTS WITH BREAST CARCINOMA USING THE VISCOELASTIC COAGULATION ASSAY"

**PI:** Dr Anupam Verma  
Medicine

**Department:** Transfusion

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

PID should reflect details of current member secretary.

Simplify Hindi PID so that is in a language easily understandable by the patient.

**Decision: Minor revision**

**Agenda No. 32**

**IEC code:** 2023-61-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Comparison of double dose Proton pump inhibitor (PPI) vs combination of single dose PPI and prokinetic in systemic sclerosis with gastroesophageal reflux disease

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The project and PID with consent documents were reviewed and the project was approved by the ethics committee.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 33**

**IEC code: 2023-62-DM-130**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Modulation of genetic markers of fibrosis and clinical scores in scleroderma following administration of Tadalafil

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The project and PID with consent documents were reviewed and the project was approved by the ethics committee.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 34**

**IEC code:** 2023-64-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Prevalence and predictors of Frailty in inflammatory myositis

**PI:** Dr Able Lawrence

**Department:** Clinical

Immunology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**The project is approved from the ethics points of view.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 35**

**IEC code:** 2023-65-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Portosystemic Shunt Surgery for Extrahepatic Portal Venous Obstruction beyond Endoscopic Variceal Eradication

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**The project is approved from the ethics points of view.**

**Agenda No. 36**

**IEC code:** 2023-70-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Evaluation of Diagnostic Performance of Type 2 Inflammatory Biomarkers in Phenotyping Patients with Chronic Obstructive Pulmonary Disease

**PI:** Dr Mansi Gupta

**Department:** Pulmonary Medicine

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

To resubmit PID for controls and participants in Hindi and English. PID to reflect the name of member secretary. It was noted that the funding will be borne by intramural funds.

Decision: Minor Revision

**Agenda No. 37**

**IEC code:** 2023-74-MD-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Red Cell alloimmunization and associated risk factors in multiply transfused thalassemia patients: A prospective cohort study conducted at Tertiary Care Centre in Northern India.

**PI:** Dr Rajendra Chaudhary

**Department:** Transfusion Medicine

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Please provide a summary of the project (Project details) as required within 500 words.**

**Waiver of consent form is incomplete. Please provide a completed form.**

To submit PID and Consent form in Hindi and English. Once submitted the project will be cleared from ethical point of view.

Decision: Minor Revision



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 38**

**IEC code:** 2023-78-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Clinical and High-Resolution Manometry spectrum of patients with esophageal motility disorders – A Retrospective Analysis.

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and waiver of consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 39**

**IEC code:** 2023-79-MD-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Assessment of quality of life and out of pocket expenses in patients with upper aerodigestive tract cancers receiving palliative chemo-radiotherapy and radiotherapy

**PI:** Dr Shagun Mishra

**Department:** Radiotherapy

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please clarify if the study is a parallel group observational study or a RCT. If it is a RCT, then the PI should follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval.

**Decision: Minor revision**

**Agenda No. 40**

**IEC code:** 2023-8-DM-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** Liver stiffness in critically ill patients with septic shock

**PI:** Dr Mohan Gurjar

**Department:** Critical Care Medicine

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 41**

**IEC code:** 2023-80-PhD-130

**Type of submission:** Project PhD

**Title of project:** Integrated statistical modelling with molecular markers to predict chronic kidney disease

**PI:** Dr Swasti Tiwari

**Department:** Molecular Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

It is noted that the study uses already collected samples. The waiver of consent form is incomplete. Please provide a completed form. Please provide the full name of the study and the ethics committee number of the study based on which samples were previously collected in the waiver form.

Please clarify why a funding of Rs 5 crore is being sought when you are only doing statistical modelling based on already collected data.

**Decision: Minor revision**

**Agenda No. 42**

**IEC code:** 2023-25-IP-130

**Type of submission:** Project Independent

**Title of project:** Retrospective Analysis Of The Double Volume Exchange Transfusions Performed In Infants At Sanjay Gandhi Post Graduate Institute Of Medical Sciences, Lucknow

**PI:** Dr Dheeraj Khetan  
Medicine

**Department:** Transfusion

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and waiver of consent documents were discussed.**

**The project is approved from the ethics points of view.**

**Agenda No. 43**

**IEC code:** 2023-54-PDCC-130

**Type of submission:** Project SRF/PDF/PDCC

**Title of project:** Extent of hemodynamic changes during Heart Repositioning in OPCAB surgery as measured by Non-calibrated Pulse Contour (FloTrac) Analysis and its Comparison with real time 3D parameters by Transesophageal Echocardiography : A Pilot Study

**PI:** Dr Prabhat Tewari

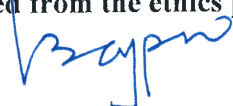
**Department:** Anaesthesiology

Primary reviewer (Technical) Dr. Durga P. Misra

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**The project is approved from the ethics points of view.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Agenda No. 44**

**IEC code:** 2023-22-IP-130

**Type of submission:** Project Independent

**Title of project:** Impediments to compliance with Clean Intermittent Catheterization in a developing country

**PI:** Dr Priyank yadav

**Department:** Urology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed in the expedited review committee meeting.**

**Clarify the total number of patients that will be included.**

**Kindly submit the Legally accepted representative and Assent form. Mention the name of Member Secretary in PID**

**The PID mentions funding of 2500 Euros. Where will these funds be utilised.**

**Kindly use the Consent form, from the institutional website.**

**Submit CV of investigator outside SGPGI.**

**Will be taken for the full board review as involves pediatric population.**

**Decision: Minor revision**

**After revision, the project is approved from the ethics points of view and ratified at the full board.**

**Agenda No. 45**

**IEC code:** 2023-24-IP-130

**Type of submission:** Project Independent

**Title of project:** Portosystemic Shunt Surgery for Extrahepatic Portal Venous Obstruction beyond Endoscopic Variceal Eradication

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Duplicate entry of 35**

**Agenda No. 46**

**IEC code:** 2023-42-IP-130

**Type of submission:** Project Independent

**Title of project:** Efficacy of intralesional injection of triamcinolone acetonide in augmentation of endoscopic dilatation of benign oesophageal strictures: a case-control study

**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The study qualifies for observational study as the committee failed to identify controls in the submitted proposal. To modify the title accordingly and replace case-control. Kindly mention the estimated sample size.

The Hindi PID/Consent should use the word “pratibhagi” for patients.

**Decision: Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 47**

**IEC code:** 2023-48-IP-130

**Type of submission:** Project Independent

**Title of project:** RADIAL SHOCK-WAVE THERAPY FOR FROZEN SHOULDER PATIENTS WITH TYPE 2 DIABETES MELLITUS: A PROSPECTIVE RANDOMISED CLINICAL TRIAL COMPARING TWO DIFFERENT ENERGY LEVELS.

**PI:** Dr Siddharth Rai

**Department:** Apex Trauma Centre

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Hindi PID is missing – please provide

Duration of study should start after ethics committee approval

Please keep in mind due methodological considerations for a RCT in line with the SPIRIT guidelines – a checklist to this should be provided. Please also calculate and justify sample size.

If this is a RCT, then the intervention should be funded/ not charged from the patient.

CTRI/ clinicaltrials.gov registration is mandatory after ethics approval before starting trial enrolment. Proof of this should be submitted to the ethics committee before starting the study.

**Decision: Revise and resubmit**

**Agenda No. 48**

**IEC code:** 2023-67-IP-130

**Type of submission:** Project Independent

**Title of project:** Practice pattern of INtraoperative FIUId therapy in elective major gaStrointestinal canceR surgeries in India (I-INFUSE)– A multicentre observational study

**PI:** Dr Sandeep Sahu

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Since this is a prospective, observational study, informed consent from patients is mandatory.

Please provide PID and ICF in English and Hindi.

PI should ensure ethics approval at all participating centers.

**Decision: Major revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 49**

**IEC code:** 2023-72-IP-130

**Type of submission:** Project Independent

**Title of project:** A study of intracranial vessel wall imaging and biomarkers in adults with primary angiitis of the central nervous system

**PI:** Dr Vinita E Mani

**Department:** Neurology

Primary reviewer (Technical): Dr. Arun Chaturvedi

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please provide PID in Hindi for patient and control.

The committee reviewed the study objectives and noted that objective 3 was not feasible to assess for a cross-sectional study (whether vessel wall imaging can replace DSA). The PI is suggested to modify this.

**Decision: Minor revision**

**Agenda No. 50**

**IEC code:** 2023-77-IP-130

**Type of submission:** Project Independent

**Title of project:** Real-life experience of retreatment with sofosbuvir/velpatasvir/voxilaprevir in treatment experienced people with chronic hepatitis C virus infection

**PI:** Dr Amit Goel

**Department:** Hepatology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Shri Sharad Jain

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The committee requests the PI to clarify if any other department was involved in the care of these patients. If so, the PI may consider including a collaborator from any other such department.

**Decision: Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 51**

**IEC code:** 2022-67-DT-130

**Type of submission:** Project Drug/device trials

**Title of project:** A randomized, double-blind, parallel group, placebo-controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of ianalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRIUS-LN)

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer Legal: Judge (Retd.) Vijai Varma

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Comments of legal reviewer:**

1-In the CTA, I could not discern the remedial measures etc, to be taken for the Trial Subject in case of Serious Adverse Event, though it does talk about the Sponsor having an Insurance cover for the Trial Subject. But that the treatment required in case of SAE shall be provided free of cost and that the cost shall be borne by the Sponsor is not there which is essential point, hence a clause to that effect be included at the appropriate place.

2-In Cl. 17, it is provided that neither party may assign its rights and obligations under this Agreement without the other Party's prior written consent but then an exception has been made that the Sponsor may assign its rights and obligations under certain conditions. Here it is necessary that the Sponsor at least gives a notice of any such assignment to the Institute/PI, lest they are caught unawares. So the provision for notice should be there.

3-In Cl 26, the jurisdiction of the courts should be Lucknow instead of Mumbai as the trial is to be conducted in Lucknow.

4-As there is no provision for dispute resolution anywhere in the CTA, hence a dispute resolution clause be added so that the matter goes to the courts only after the dispute is not settled amicably between the parties.

5-In Cl.14 pertaining to the Confidentiality clause it is provided as to under what circumstances the Institute or the PI can disclose the information which otherwise they can not disclose. But herein it should also be provided that the Institute/PI can also disclose the information in compliance of any requirement of law, rules regulations or any govt order, hence such a provision be made in this clause itself.

6- The Insurance policy has lapsed on 31.12.2022 whereas the study is to continue till 01.04.2031, hence the Insurance policy needs to be extended till the completion of the study.

**Decision: Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 52**

**IEC code:** 2023-75-DT-130

**Type of submission:** Project Drug/device trials

**Title of project:** A prospective, interventional, multicenter, Phase IV, open-label, single arm study to assess the safety and effectiveness of finerenone in participants from India with chronic kidney disease associated with type 2 diabetes

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer Legal: Judge (Retd.) Vijai Varma

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Comments of legal reviewer:**

1-The most important issue in this CTA is that the Sponsor is not a party to this agreement but it is a third party beneficiary. The Sponsor has appointed a CRO Parexel International Clinical Research Pvt Ltd. But from the CTA it transpires that the Sponsor has to discharge a number of functions and obligations as the Institute and the PI also have to. But in case there is any breach of the provisions of this CTA by the Institute or the PI then the Sponsor can proceed against the Institute or the PI as the case may be but in case the Sponsor fails to discharge any of its obligations then the Institute or the PI can not proceed against the Sponsor as it is not a party to the Agreement. Therefore the Sponsor should also be arrayed as party or at least be a signatory to this agreement.

2-In Cl.20.8 it is provided that the CRO may assign this agreement to any of its Subsidiaries, Affiliates or to a third Party. But here a notice of such assignment should be given to the Institute/PI.

3- There is no provision for resolution of the disputes in this CTA, hence a provision to that effect be added. However in case the dispute is not amicably settled between the parties, the matter may be taken to the courts at Lucknow instead of Bangalore as the study is to be conducted in Lucknow only.

4- The Insurance policy is expiring on 31.12.2023 whereas the study is to continue till 30.12.2025, hence the policy needs to be extended till the completion of the study.

**Decision : Minor revision**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 53**

**IEC code:** 2023-76-DT-130

**Type of submission:** Project Drug/device trials

**Title of project:** A Randomized, Multi Center, Parallel, Open Label Study Assessing Clinical and Functional Outcomes After Anterior Cruciate Ligament (ACL) Reconstruction Procedure Using Suspensory Tibial Fixation with Open and Closed Peek Button

**PI:** Dr Pulak Sharma

**Department:** Apex Trauma Centre

Primary reviewer (Technical): Dr. Uday C. Ghoshal

Primary reviewer Legal: Judge (Retd.) Vijai Varma

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

At places in the protocol it is mentioned as cohort study and at others it is mentioned as RCT. Please clarify.

If it is a RCT, then randomization should be done before surgery.

If it is a RCT, then it will require CTRI registration and DCGI approval.

It is recommended to include a co-PI from the same Department

The PID should include the details of PI and the Member Secretary of ethics committee.

PI should ensure ethics approval from all the collaborating centers.

Legal reviewer comments;

1- The record is to be kept for 15 years. It is to be ensured that the fees for keeping the records for such a long period is being paid by them or not. If not then may make a demand.

Decision: Major revision

**Agenda No. 107**

**IEC code:** 2023-82-MD-130

**Type of submission:** Project DM/MCh/MD

**Title of project:** A Prospective Study of Locally Advanced, Unresectable/ Inoperable, Good Performance Status, Upper Aerodigestive Tract Carcinoma Patients, Randomised Between Palliative Regimens – 70Gy/35# vs. 30Gy/10#

**PI:** Dr Sushma Agrawal

**Department:** Radiotherapy

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please clarify if the study is a parallel group observational study or a RCT. If it is a RCT, then the PI should follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval.

Decision: Minor revision

**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 108**

**IEC code:** 2023-83-EMP-130

**Type of submission:** Project Extramural

**Title of project:** Soul of Steel-Himalayan

**PI:** Dr Prabhaker Mishra

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Department:** Biostatistics

**Please provide PID and ICF in Hindi.**

**Please provide forwarding from HoD and DRC.**

**Decision: Minor revision**

**Agenda No. 109**

**Type of submission: Project DM/MCh/MD**

**Title of project: Prospective study of locally advanced, unresectable/inoperable, poor performance status, upper aerodigestive tract carcinoma, randomised between palliative regimens - 20Gy/5 fractions vs 14Gy/4 fractions (Quad shot)**

**PI:** Dr Shalini Singh

**Department:** Radiotherapy

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr Shalini Mathur

**Scientific issues, ethical issues and informed consent documents were discussed.**

Please clarify if the study is a parallel group observational study or a RCT. If it is a RCT, then the PI should follow the recommended methods of formulating a randomized trial ( randomization method, blinding, sample size calculation, allocation concealment, etc). The study design in case of RCT should be reflected in the title. The PID and the consent form need to be designed separately for the control & experimental group. In the case of a RCT, CTRI/ clinicaltrials.gov registration would be necessary before starting the trial after obtaining ethics approval.

**Decision: Minor revision**

**D. Notification for Amendments/Addendum:**

**Agenda No. 54**

**IEC code:** 2019-195-DM-113

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** To assess and compare microvascular and macrovascular complications in early and late onset type 2 diabetes

**PI:** Dr Subhash Yadav

**Department:** Endocrinology

**Subject:** Amendment report (Adding one DM student Dr Ayushi Singhal)

Noted and approved.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Agenda No. 55**

**IEC code:** 2020-196-DT-115

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Amendment report (Amendment 4 study related documents along-with summary of changes and Intimation letter for the change in the name of Sponsor).

**Noted and approved.**

**Agenda No. 56**

**IEC code:** 2021-131-DM-120

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Usefulness and accuracy of FibroScan in diagnosing biliary atresia and predicting prognosis following Kasai portoenterostomy: A prospective Case Control Study

**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

**Subject:** Amendment report (Inclusion criteria and Exclusion criteria etc.)

**Noted and approved.**

**Agenda No. 57**

**IEC code:** 2021-270-EMP-123

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Feasibility of a new diagnostic device to assess small intestinal dysbiosis in routine clinical setting

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

**Subject:** Amendment report (A small subset of patients will be asked to ingest 2 capsules simultaneously on the same day and Change PID)

**Noted and approved.**

**Agenda No. 58**

**IEC code:** 2021-346-DT-124

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Diseasesubcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** Amendment report (Amended protocol V 3.0 dated 27 Oct 2022 & Protocol V 3.0 - List of Changes)



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Noted and approved.**

**Agenda No. 59**

**IEC code:** 2021-347-DT-124

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A Prospective, Open-Label, Multicentered, Non-Randomized, Non-Comparative Active Post-Marketing Surveillance to test the safety and efficacy of Diperoxochloric Acid [DPOCL] topical solution in patients with diabetic neuropathic ulcers of skin and subcutan

**PI:** Dr Gyan Chand

**Department:** Endocrine Surgery

**Subject:** Amendment report ( Request 6 months extra time requirement for completion of study due to festival and summer vacation).

**Noted and approved.**

**Agenda No. 60**

**IEC code:** 2021-96-PhD-EXP-37

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Circulating Microparticles and their Fibrogenic Activity in Renal Allograft Dysfunction

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Amendment report (the second objective is to study the fibrogenic activity of circulating MPs on human renal fibroblast cell (Nephrectomy) by evaluating the expression of cytokine TGF- $\beta$ 1).

**Noted and approved.**

**Agenda No. 61**

**IEC code:** 2022-25-DT-125

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A streamlined, multicentre, randomized, parallel group, double-blind placebo-controlled superiority trial to evaluate the effect of EMPAgliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Amendment report (Study related documents Protocol version 2.0 dated 20th Apr 2022).

**Noted and approved.**

**E. Notification for protocol deviation:**

**Agenda No. 62**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Dr Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Notification for protocol deviation( Subject ID: 41050100, 41050118, 41050266).

**Noted and approved.**

**Agenda No. 63**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Notification for protocol deviation ( Subject ID: 2100003, SB).

**Noted and approved.**

**Agenda No. 64**

**IEC code:** 2021-178-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Notification for protocol deviation (Subject ID: 2051001, D1 visit and D14 visit).

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 65**

**IEC code:** 2021-178-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Notification for protocol deviation (Subject ID: 2051001 , D30 visit).

**Noted and approved.**

**Agenda No. 66**

**IEC code:** 2021-180-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Notification for protocol deviation ( Subject no: 2224002).

**Noted and approved.**

**F. General Notification:**

**Agenda No. 67**

**IEC code:** 2019-178-DT-111

**Type of submission:** General Notification

**Title of project:** Protocol I4V-MC-JAHU: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less than 18 years Old with Systemic Juvenile Idiopathic Arthritis.

**PI:** Dr Amita Aggarwal

**Department:** Clinical

Immunology

**Subject:** Baricitinib, LY3009104, IB approved on 14 Dec 2022.

**Noted and approved.**

**Agenda No. 68**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Updated Insurance policy ( Ploicy no: 4067/192797058/00/000)

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 69**

**IEC code: 2020-286-DT-116**

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of DSUR 15 Oct 2021 to 14 Oct 2022.

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 70**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from 01 May 2022 to 31 Jul 2022.

**Noted and approved.**

**Agenda No. 71**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** SUSAR Line Listing Report form 15 Apr 2022 to 14 Aug 2022 for IEC notification.

**Noted and approved.**

**Agenda No. 72**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from 01 Aug 2022 to 31 Oct 2022.

**Noted and approved.**

**Agenda No. 73**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

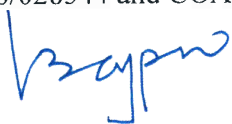
**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Study related documents (Request for extension of IEC approval, SIV conduct, CTRI no: CTRI/2020/10/028544 and COA dated 31-Mar-2022).

**Noted and approved.**

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 74**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Study related documents for IEC approval (document submit date :02-02-2023).

**Noted and approved.**

**Agenda No. 75**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Notification of EUROPEAN Medicines Agency review on Crizanlizumab study

**Noted and approved.**

**Agenda No. 76**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Updated Insurance on Crizanlizumab study (Policy no: P052320001/9999/100188).

**Noted and approved.**

**Agenda No. 77**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** ECOG status not taken on upcoming visit as per protocol.

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 78**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Study Related documents (417-201-00007 BUN Urea and Bicarbonate Testing V01 dated 24 Oct 2022, 417-201-00007 Protocol Clarification Memo Protocol Amendment Dated 18 Nov 2022, Otsuka Pharmaceutical Development & Commercialization Inc 417-201-00007-SP6309-(

**Noted and approved.**

**Agenda No. 79**

**IEC code:** 2021-178-DT-121

**Type of submission:** General Notification

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Study related documents for review and approval IB Edi 9 Release date 29- Jan 2022 and IB Summary of Changes.

**Noted and approved.**

**Agenda No. 80**

**IEC code:** 2021-178-DT-121

**Type of submission:** General Notification

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** SUSAR in LNP023 listing covering the period 01 April 2022 to 30 September 2022.

**Noted and approved.**

**Agenda No. 81**

**IEC code:** 2021-179-DT-121

**Type of submission:** General Notification

**Title of project:** A multicenter, single-arm, open label trial to evaluate efficacy and safety of oral, twice daily LNP023 in adult aHUS patients who are naïve to complement inhibitor therapy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Study related documents (IB edi 9, Release date 29-Jun-2022 and IB Summary of Changes).

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



Noted and approved.

**Agenda No. 82**

**IEC code:** 2021-179-DT-121

**Type of submission:** General Notification

**Title of project:** A multicenter, single-arm, open label trial to evaluate efficacy and safety of oral, twice daily LNP023 in adult aHUS patients who are naïve to complement inhibitor therapy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Study related documents for IEC approval submit on 23 Feb 2023.

Noted and approved.

**Agenda No. 83**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Study related documents for IEC notification (IB\_OMB157/Ofatumumab-(Edition 07th Nov 2022, IB\_ OMB157/Ofatumumab Summary of Changes (Edition 07th Nov 2022).

Noted and approved.

**Agenda No. 84**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Study related documents for IEC notification (CBAF312 (L1)SUSAR (s), CFTY720 (L1)SUSAR (s), COMB157\_NON OCOLOGY (L1)SUSAR (s) dated 01 Apr 2022 - 30 Sep 2022).

Noted and approved.

**Agenda No. 85**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Subject no:2224002 discontinue from study on 22 Dec 2022.

Noted and approved.



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 86**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Study related documents of IEC notification (Data Monitoring Committee letter dated 23 Jan 2023).

**Noted and approved.**

**Agenda No. 87**

**IEC code:** 2021-227-DT-122

**Type of submission:** General Notification

**Title of project:** A randomized, Open label, Single Center, Post Market Clinical Study to Evaluate the Efficacy and Safety of a New Antimicrobial Wound Dressing (VELVERT) Compared to Standard dressing (SD) in the treatment of Diabetic Foot Ulcer

**PI:** Dr Gyan Chand

**Department:** Endocrine Surgery

**Subject:** Renewed Insurance documents (policy no: 4067/230369882/01/000).

**Noted and approved.**

**Agenda No. 88**

**IEC code:** 2021-271-EMP-123

**Type of submission:** General Notification

**Title of project:** Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide as a radiation sensitizer in patients with locally advanced/recurrent breast cancer.

**PI:** Dr Punita Lal

**Department:** Radiotherapy

**Subject:** Study related documents for review and approval (CTRI no: CTRI/2022/02/040331, policy no: 93000036220200000004, Protocol version: 3.0 dated 1.11.2021 along with summary changes, PID, eCRF, DCGI approval for the latest version)

**Noted and approved.**

**Agenda No. 89**

**IEC code:** 2021-346-DT-124

**Type of submission:** General Notification

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease subcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** Insurance letter for IEC notification (Insurance no: OG-23-1113-3306-00000003 and policy period from 11-May-2022 to 10-May-2023)

**Noted and approved.**

**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 90**

**IEC code:** 2021-346-DT-124

**Type of submission:** General Notification

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease subcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** CTRI registry for review and IEC notification (CTRI no: CTRI/2021/12/038690)

**Noted and approved.**

**Agenda No. 91**

**IEC code:** 2021-346-DT-124

**Type of submission:** General Notification

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease subcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** Sponsor changing documents for review and IEC notification

**Noted and approved.**

**Agenda No. 92**

**IEC code:** 2021-346-DT-124

**Type of submission:** General Notification

**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease subcutaneous tissue.

**PI:** Dr Kausik Mandal

**Department:** Medical Genetics

**Subject:** Signed CTA for IEC notification

**Noted and approved.**

**Agenda No. 93**

**IEC code:** 2022-177-DT-129

**Type of submission:** General Notification

**Title of project:** An Adaptive, randomized, double blind, dose exploration, parallel group, placebo-controlled, multicenter, phase 2 trial to evaluate the efficacy, safety and tolerability of LNP023 in combination with standard of care with or without oral combination corti

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Study related documents ( IB edi 9, Release date 29-Jun-2022 and IB Summary of Changes).

**Noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 94**

**IEC code:** 2022-177-DT-129

**Type of submission:** General Notification

**Title of project:** An Adaptive, randomized, double blind, dose exploration, parallel group, placebo-controlled, multicenter, phase 2 trial to evaluate the efficacy, safety and tolerability of LNP023 in combination with standard of care with or without oral combination corti

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Updated Investigator Undertaking dated 02-Jan-2023

**Noted and approved.**

**Agenda No. 95**

**IEC code:** 2022-72-DT-128

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Study related documents for IEC approval ( Retention Item Plan dated V2.0 dated 02 Nov 2022).

**Noted and approved.**

**Agenda No. 96**

**IEC code:** 2022-72-DT-128

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** DCGI NOC letter dated 16 Sep 2022.

**Noted and approved.**

**Agenda No. 97**

**IEC code:** 2022-72-DT-128

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology


**Subject:** Insurance Certificate ( Ploicy no: D068507958).

**Noted and approved.**

**Agenda No. 98**

**IEC code:** 2022-72-DT-128

**Type of submission:** General Notification

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** CTRI registration confirmation dated 23 Nov 2022 (CTRI no: CTRI/2022/11/047572).

**Noted and approved.**

**Agenda No. 99**

**IEC code:** 2022-72-DT-128

**Type of submission:** General Notification

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** IRB waiver letter study no: 417-201-0007

**Noted and approved.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 100**

**IEC code:** 2019-19-RA-EXP-7

**Type of submission:** Final/Annual/Progress reports

**Title of project:** "Genetic risk factors and biomarkers of Non- alcoholic fatty liver disease".

**PI:** Dr Samir Mohindra

**Department:** Gastroenterology

**Subject:** Annual Progress report (document submit dated 21-02-2023)

**Noted and approved.**

**Agenda No. 101**

**IEC code:** 2020-329-DT-117

**Type of submission:** Final/Annual/Progress reports

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Annual Progress report (Document submit date 11-01-2023).

**Noted and approved.**

**Agenda No. 102**

**IEC code:** 2021-125-IMP-120

**Type of submission:** Final/Annual/Progress reports

**Title of project:** To study the effect of medical nutrition therapy to alleviate school time hyperglycemia and address glycemic outcomes in children with type 1 diabetes mellitus

**PI:** Dr Siddhnath Sudhanshu

**Department:** Endocrinology

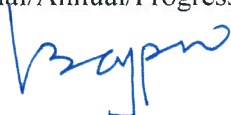
**Subject:** Annual Progress report (Document submitted on 08-02-2023).

**Noted and approved.**

**Agenda No. 103**

**IEC code:** 2021-180-DT-121

**Type of submission:** Final/Annual/Progress reports



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Annual Progress report (Document Submit date 11-01-2023).

**Noted and approved.**

**Agenda No. 104**

**IEC code:** 2018-118-IMP-105

**Type of submission:** Study Close out Notification

**Title of project:** vitamin D deficiency and its replenishment in children with epilepsy receiving antiepileptic drugs.

**PI:** Dr Siddhnath Sudhanshu

**Department:** Endocrinology

**Subject:** Study completion report (completion date: Oct 2022).

**Noted and approved.**

**Agenda No. 105**

**IEC code:** 2020-18-MD-114

**Type of submission:** Study Close out Notification

**Title of project:** A PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS THE EFFICACY OF AURICULAR TENS IN PAIN RELIEF AND HEMODYNAMICS IN POST STERNOTOMY CARDIAC SURGICAL PATIENTS.

**PI:** Dr Prabhat Tewari

**Department:** Anaesthesiology

**Subject:** Study completion report (completion date: Aug 2021).

**Noted and approved.**

**Agenda No. 106**

**IEC code:** 2021-97-IMP-EXP-38

**Type of submission:** Study Close out Notification

**Title of project:** Antibody response to Covid-19 vaccination in patients with advanced liver disease

**PI:** Dr Amit Goel

**Department:** Gastroenterology

**Subject:** Study completion report (completion date: December 2021).

**Noted and approved.**



(Dr. Durga P. Misra)  
Member Secretary,  
IEC, SGPGI



(Dr. M.K. Mitra)  
Chairman,  
IEC, SGPGI



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 129<sup>th</sup> Institutional Ethics Committee** meeting held on 15<sup>th</sup> December 2022, at 2:30 PM, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

**Present:**

1. Prof. M. K. Mitra, Retd. Professor, Dept. of Medicine, KGMU, Lucknow	Chairperson
2. Prof. Shubha Phadke, Acting Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Ex-Officio Member
3. Dr. Gautam Palit, Former Chief Scientist and Head, Dept. of Pharmacology, CSIR, Lucknow	Member
4. Dr. Arun Chaturvedi, Retd. Head, Dept. of Oncology, KGMU, Lucknow	Member
5. Dr. Mala Kumar, Professor, Department of Pediatric, KGMU, Lucknow	Member
6. Dr. Uday C. Ghoshal, Prof. & Head, Department of Gastroenterology, SGPGI MS, Lucknow	Member
7. Dr. Vinita Agarwal, Professor, Department of Pathology, SGPGIMS, Lucknow	Member
8. Prof. Anand Vishwakarma, Professor of Law and Director Legal Cell, University of Lucknow	Member
9. Shri. Vijai Varma Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
10. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
11. Shri Sharad Jain, Shri Madhav Seva Ashram, Lucknow	Member
12. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
13. Mr. Anil Kumar Srivastava, Retd. Professor, Department of Sociology, University of Lucknow	Member
14. Dr. Shagun Mishra, Additional Professor, Department of Radiotherapy, SGPGIMS, Lucknow	Alternate Member Secretary
15. Dr. Durga P. Misra, Associate Professor, Department of Clinical Immunology, SGPGIMS, Lucknow	Member Secretary

**Determination of quorum:** quorum was complete: 12 members present, with 7 non-institutional members.

**A: General discussions and confirmation of Minutes:**

**Approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 128th IEC meeting held on 24.09.2022. All the members of IEC approved the minutes of the meeting.



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Executive Registrar  
SGPGIMS, Lucknow

**B. Review of New Proposals:**

**Agenda No. 1**

**IEC code:** 2022-164-EMP-129

**Type of submission:** Project Extramural

**Title of project:** Acceptability and Usability of Hepatitis-C Self-Testing and its Distribution Models among the General Population, and People Who Inject Drugs and their Partners in India

**PI:** Dr Amit Goel

**Department:** Gastroenterology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. The project is approved from the ethics points of view.**

**Agenda No. 2**

**IEC code:** 2022-166-EMP-129

**Type of submission:** Project Extramural

**Title of project:** Role of Zr89-Rituximab PET/CT in Rheumatoid Arthritis patients: A pilot study

**PI:** Dr S Gambhir

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. The PID is written in the form of instructions for making the PID rather than as a patient information to the PID. Please modify it.**

**Please also provide a Hindi version of the PID.**

**Decision:** Minor revision

**Agenda No. 3**

**IEC code:** 2022-167-EMP-129

**Type of submission:** Project Extramural

**Title of project:** Analysis of placental derived Extracellular vesicles for aneuploidy detection

**PI:** Dr Swasti Tiwari

**Department:** Molecular Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. Please clarify the investigator who shall be responsible for recruiting pregnant patients into the study. It is suggested to include an investigator from a relevant clinical background for this purpose.**

**Decision:** Minor revision

**Agenda No. 4**

**IEC code:** 2022-169-EMP-129

**Type of submission:** Project Extramural

**Title of project:** MOLECULAR TAXONOMY TO DEFINE SEVERITY AND PROGNOSIS OF HEAD INJURY

**PI:** Dr Pawan Kumar Verma

**Department:** Neurosurgery

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 5**

**IEC code:** 2022-179-DT-129

**Type of submission:** Project Extramural

**Title of project:** A Prospective, openlabelled, Multicenter, Observational, Registry of ISAR SUMMIT IN CAD Patients undergoing PCI in real world indian population (TRANSEVER REGISTRY).

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 6**

**IEC code:** 2022-180-DT-129

**Type of submission:** Project Extramural

**Title of project:** Prevalence, determinants and awareness of covert injuries and its effect on performance in players involved in non contact sports

**PI:** Dr Pulak Sharma

**Department:** Apex Trauma Centre

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
Please provide for review**

- Hindi informed consent form for patient

- English and Hindi informed consent form for parent consent & for child assent.

**Decision:** Minor revision

**After revision, the project was approved from the ethics points of view.**

**Agenda No. 7**

**IEC code:** 2022-161-MD-129

**Type of submission:** Project DM/MCh/MD

**Title of project:** Comparison of effect of Cricoid and Paratracheal pressure on patency of upper esophagus, under General Anaesthesia

**PI:** Dr Divya Srivastava

**Department:** Anaesthesiology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Please clarify when consent shall be taken.**

**Question 9 in the PID is blank, please fill it.**



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**Decision: Minor revision**

**Agenda No. 8**

**IEC code: 2022-162-MD-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Role of lenvatinib as adjuvant to high dose I-131 therapy in bulky metastatic thyroid cancer

**PI:** Dr Manish Ora

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Please clarify whether lenvatinib is approved for the indication.**

**The invitation paragraph of PID should mention that you are being invited to participate in the study as you have bulky metastatic thyroid cancer.**

**It is suggested to clarify/involve an investigator who is experienced with the usage of this drug for the monitoring of adverse events.**

**Decision: Minor revision**

**Agenda No. 9**

**IEC code: 2022-165-MD-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** 11C-PIB PET/CT IN SUSPECTED PATIENTS OF DEMENTIA AND MILD COGNITIVE IMPAIRMENT: VALUE ADDITION OVER STANDARD CLINICO-IMAGING WORK UP -A PILOT STUDY

**PI:** Dr S Gambhir

**Department:** Nuclear Medicine

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Please provide Hindi version of PID**

**Please provide a PID for the legally acceptable representative who shall be involved in the consent process.**

**Decision: Minor revision**

**Agenda No. 10**

**IEC code: 2022-168-MD-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Evaluation of the postoperative olfactory and gustatory dysfunction following gargle with 2% lignocaine hydrochloride oral topical solution and nebulization with 4% lignocaine in the patients undergoing fiberoptic intubation for cervical spine surgery and

**PI:** Dr Devendra Gupta

**Department:** Anaesthesiology

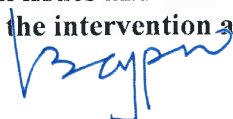
Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

**Please clarify which is the intervention and which is the control group.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

After ethics approval, the investigator should get the trial registered by CTRI and start enrollment after CTRI registration. At this stage, a copy of the CTRI registration should be submitted to the IEC before starting the study.

**Decision: Minor revision**

**Agenda No. 11**

**IEC code: 2022-170-DM-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Transcranial Magnetic stimulation treatment for New Daily persistent Headache, Single Arm Open Label study

**PI:** Dr Vimal Kumar Paliwal

**Department:** Neurology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. The project is approved from the ethics points of view.**

**Agenda No. 12**

**IEC code: 2022-174-MD-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Comparison of placement efficacy of inflatable cuff & non-inflatable cuff supraglottic airway device when used by trainee anaesthesiologists in patients under general anaesthesia

**PI:** Dr Amit Rastogi

**Department:** Anaesthesiology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. The title in the protocol submitted to PG committee is different from the one submitted to the IEC. The title should include randomized controlled trial.**

**Please provide informed consent form – in English and Hindi**

After ethics approval, the investigator should get the trial registered by CTRI and start enrollment after CTRI registration. At this stage, a copy of the CTRI registration should be submitted to the IEC before starting the study.

**Decision: Minor revision**

**Agenda No. 13**

**IEC code: 2022-175-DM-129**

**Type of submission:** Project DM/MCh/MD

**Title of project:** Screening for Iron overload in Wilson disease

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed. The project is approved from the ethics points of view.**

**Agenda No. 14**

**IEC code: 2022-199-MD-129**



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**Type of submission:** Project DM/MCh/MD

**Title of project:** To compare the intrathecal hyperbaric Levobupivacaine with morphine verses hyperbaric Bupivacaine with morphine for postoperative analgesia after LSCS, a prospective randomised double blind study

**PI:** Dr Sandeep Sahu

**Department:** Anaesthesiology

Primary reviewer (Technical) Dr. Durga P. Misra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**After ethics approval, the investigator should get the trial registered by CTRI and start enrollment after CTRI registration. At this stage, a copy of the CTRI registration should be submitted to the IEC before starting the study.**

**Agenda No. 15**

**IEC code:** 2022-163-IP-129

**Type of submission:** Project Independent

**Title of project:** Antibody response to rapid course of hepatitis B vaccine among people who inject drug (PWID) in India

**PI:** Dr Amit Goel

**Department:** Gastroenterology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**Agenda No. 16**

**IEC code:** 2022-171-IP-129

**Type of submission:** Project Independent

**Title of project:** Evaluation of intubation performances of Glidescope versus Smart trach videolaryngoscopes in infants. A randomized prospective clinical trial

**PI:** Dr Rudrashish Halder

**Department:** Anaesthesiology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.  
The project is approved from the ethics points of view.**

**After ethics approval, the investigator should get the trial registered by CTRI and start enrollment after CTRI registration. At this stage, a copy of the CTRI registration should be submitted to the IEC before starting the study.**

**Agenda No. 17**

**IEC code:** 2022-172-CP-129

**Type of submission:** Project Collaborative

**Title of project:** Genetics of Takayasu arteritis and other immune-mediated diseases.

**PI:** Dr Durga Prasanna Misra

**Department:** Clinical Immunology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Scientific issues, ethical issues and informed consent documents were discussed.  
Kindly inform the number of patients that will be accrued from the participating institution**

**Please mention about ethics approval of the participating institution**

**To submit material transfer agreement/HMSC approval after ethics approval.**

**Decision: Minor revision.**

**Agenda No. 18**

**IEC code: 2022-176-DT-129**

**Type of submission:** Project Drug/device trials

**Title of project:** A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of remibrutinib versus teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label remibrutinib

**PI:** Dr Jayantee Kalita

**Department:** Neurology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The PI is requested to synthesize a concise PID in addition to the one that has already been provided, for the ease of the patients being recruited.

Legal reviewer comments:

1- Insurance policy is expiring on 31.12.2022 whereas the study end date is 31.07.2030.hence the policy needs to be extended till the date of the completion of the study.

2-In clearly.17 of the CTA, it is provided that the Novartis may assign its rights and obligations under the Agreement to its Affiliates etc. but there is no provision for giving notice to the Institution/PI .Though the Sponsor has a right to do so but at least a notice of the same may be given to the Institution/PI, so that they are not caught unawares.

3- In cl.26, the jurisdiction of the courts at Mumbai is given.It may be changed to Lucknow as the Study is to be undertaken at Lucknow.

4-There is no provision for the dispute resolution in the CTA. Let a clause be added for providing the mechanism for dispute resolution if an occasion so arises.

5-In the ICF, it is provided in para9 that all costs for the required visits etc. shall be provided by the Sponsor to the participants but at the same time it is also mentioned that the participants will still be responsible for the usual costs for their medication which appears to be slightly unethical.

Decision: Minor revision

**Agenda No. 19**

**IEC code: 2022-177-DT-129**

**Type of submission:** Project Drug/device trials

**Title of project:** An Adaptive, randomized, double blind, dose exploration, parallel group, placebo-controlled, multicenter, phase 2 trial to evaluate the efficacy, safety and tolerability of LNP023 in combination with standard of care with or without oral combination corti

**PI:** Dr DS Bhadauria

**Department:** Nephrology

Primary reviewer PID and CF: Dr. Shagun Mishra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**



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Executive Registrar  
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The PI is requested to synthesize a concise PID in addition to the one that has already been provided, for the ease of the patients being recruited.

1-The Insurance policy is expiring on 31.12.2022 whereas the Study End Date is 01.08.2025 hence the Policy needs to be extended till the completion of the Study.

2-The issues raised at point no. 2 to 4 of Agenda item no.18 are reiterated here as the Sponsor's CTA is exactly the same here.

3-In cl.8 of the ICF in a query as to what happens if I (the participant) is injured due to his participation in the study, it is mentioned that for this point he should see section in the core informed consent, which appears to be little improper as he can be explained here only, in specific terms as to how he will be dealt with in such a situation.

Decision: Minor revision

**Agenda No. 20**

**IEC code:** 2022-178-DT-129

**Type of submission:** Project Drug/device trials

**Title of project:** A Phase 3, Multi-Center, Randomized, Open-Label, Assessor-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

The PI is requested to synthesize a concise PID in addition to the one that has already been provided, for the ease of the patients being recruited.

Kindly ensure that there is minimal spillage of the Mino-lok solution into the bloodstream to avoid any adverse effects.

Decision: Minor revision

**Agenda No. 21**

**IEC code:** 2022-181-DT-129

**Type of submission:** Project Drug/device trials

**Title of project:** A prospective, randomized, assessor-blind, active controlled, multi-center study to demonstrate the safety and efficacy of VELGRAFT, an allogenic cell-based wound dressing, in comparison to standard moist wound dressing in management of chronic diabetic foot

**PI:** Dr Gyan Chand

**Department:** Endocrine Surgery

Primary reviewer (Technical): Dr Vinita Agrawal

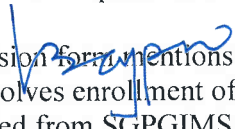
Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

**Scientific issues, ethical issues and informed consent documents were discussed.**

1. DCGI has approved the study as a Phase I study, after which an interim analysis is required for the permission for Phase II study. The PI would require permission from DCGI and the IEC for approval of the phase II study after interim analysis of phase I study.

2. The project submission form mentions 100 participants. Possibly it is for the Phase II study. Phase I study involves enrollment of 24 participants only. Clarify the number of participants to be enrolled from SGPGIMS (out of the 24). Kindly check and correct.

  
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3. Exclusion criteria mention that 'patients with cellulitis and other infections would be excluded'. Swab for the same will be taken. Kindly ensure in the 'inclusion criteria' that participants are included in the study only after the swab culture report is reported negative.

4-In cl.2.4 of the CTA, it is provided that if the PI is unwilling or unable to perform the study then a replacement is to be found by the Institution with consultation of the Sponsor. However if no such replacement is found then the study could be continued with Prof.Gyan Chand.Here there appears to be some fallacy as Prof.Gyan Chand is the PI himself and if he is unwilling or unable to perform the study, then how can he be asked to continue with the study.

Decision: Minor revision.

**After revision, the project was approved from the ethics points of view.**

### **C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee:**

The recommendation of the Member Secretary/Expedite Review Committee for the agenda 22 to 46 (EXP meeting no. 49) who has given clearance for the proposals has been approved by the committee.

#### **Agenda No. 22**

**IEC code:** 2022-117-IP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Causes of delay in diagnosis of SLE patients in India.

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 23**

**IEC code:** 2022-118-CP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Laryngotracheal and Upper airway symptoms due to mechanical ventilation after orotracheal intubation in Critically ill patients - a Prospective Multicentre Cohort study

**PI:** Dr Mohan Gurjar

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 24**

**IEC code:** 2022-120-IMP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** An Retrospective Study to Assess the Functional Outcomes Ater Anterior Cruciate Ligament Reconstruction Using an Adjustable Loop Button and PLDLA-BTCP Interference screw

**PI:** Dr Pulak Sharma

**Department:** Apex Trauma Centre

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 25**

**IEC code:** 2022-122-IMP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Functional validation of the micro-RNAs involved in the pathogenesis of acquired Aplastic anemia.

**PI:** Dr Ruchi Gupta

**Department:** Clinical Hematology

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 26**

**IEC code:** 2022-123-IMP-EXP-49

**Type of submission:** Expedite review project for IEC notification



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Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** Standardization and validation of in-house methods for Adams-13 activity and anti-CFH antibody

**PI:** Dr Dinesh Chandra

**Department:** Clinical Hematology

**Subject:** Expedite review project for IEC notification

**Agenda No. 27**

**IEC code:** 2022-124-IMP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Comparative evaluation of diagnostic and prognostic accuracy of Procalcitonin, CD64, Group II phospholipase a 2 and Human neutrophil lipocalin for adult septic shock patients admitted in Emergency Department.

**PI:** Dr Tanmoy Ghatak

**Department:** Emergency Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 28**

**IEC code:** 2022-126-IMP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Role of multiplex real time PCR assay in the diagnostic evaluation of granulomatous inflammation due to Tuberculosis

**PI:** Dr Mansi Gupta

**Department:** Pulmonary Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 29**

**IEC code:** 2022-127-MD-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Profiling of O group donors according to antibody titers

**PI:** Dr Prashant Agarwal

**Department:** Transfusion Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 30**

**IEC code:** 2022-128-IP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Assessment of awareness of Emergency Medicine (EM) amongst medical students, faculties and medical practitioners in India

**PI:** Dr Om Prakash Sanjeev

**Department:** Emergency Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 31**

**IEC code:** 2022-129-IP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Retrospective Observation Study of Tropical Pulmonary Eosinophilia

**PI:** Dr Ajmal Khan

**Department:** Pulmonary Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 32**

**IEC code:** 2022-131-DM-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** P-glycoprotein expression and function on peripheral blood lymphocytes in Takayasu arteritis.

**PI:** Dr Durga Prasanna Misra

**Department:** Clinical Immunology

**Subject:** Expedite review project for IEC notification

**Agenda No. 33**

**IEC code:** 2022-132-EMP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Study the molecular mechanism of nephrolithiasis and screening of potential therapeutics for disease by using Drosophila model

**PI:** Dr Naveen Kumar Gautam

**Department:** Urology

**Dr Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Subject:** Expedite review project for IEC notification

**Agenda No. 34**

**IEC code:** 2022-136-CP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Practice pattern of aerosol therapy in ICU/Emergency Department patients (AERO-IN ICU/ED)

**PI:** Dr Mohan Gurjar

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 35**

**IEC code:** 2022-137-IP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Evaluation of HBeAg positive status as a surrogate marker of high HBV DNA requiring antiviral treatment in pregnant Indian women: a multicentric retrospective review of data

**PI:** Dr Amit Goel

**Department:** Gastroenterology

**Subject:** Expedite review project for IEC notification

**Agenda No. 36**

**IEC code:** 2022-138-IP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** "Risk factors and early prediction of Post-Endoscopic Retrograde Cholangiopancreatography Pancreatitis (PEP) in children"

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Expedite review project for IEC notification

**Agenda No. 37**

**IEC code:** 2022-139-CP-EXP-49

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Worldwide Delirium 1-Day Point Prevalence Study 2023

**PI:** Dr Mohan Gurjar

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 38**

**IEC code:** 2022-108-IMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Effect of Three Months Daily Teriparatide Injection in Osteoporotic Intertrochanteric fractures: A Randomised Controlled Trial

**PI:** Dr Kumar Keshav

**Department:** Apex Trauma Centre

**Subject:** Clarification submitted by Dr Kumar Keshav Dept. of Apex Trauma Centre and approved by Member Secretary for notification

**Agenda No. 39**

**IEC code:** 2022-111-IMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Comparison of the use of LMA Gastro Airway versus sedation and oxygen supplementation with nasal cannula in patients undergoing Endoscopic Retrograde Cholangiopancreatography: A Prospective Randomised Control Study

**PI:** Dr Suruchi

**Department:** Anaesthesiology

**Subject:** Clarification submitted by Dr Suruchi Dept. of Anaesthesiology and approved by Member Secretary for notification

**Agenda No. 40**

**IEC code:** 2022-112-CP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** EUS-guided trans-papillary or trans-luminal biliary stenting for malignant biliary obstruction: A prospective randomised comparison

**PI:** Dr Praveer Rai

**Department:** Gastroenterology

**Subject:** Clarification submitted by Dr Praveer Rai Dept. Of Gastroenterology and approved by Member Secretary for notification

**Agenda No. 41**

**IEC code:** 2022-113-EMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Efficacy and safety of levodopa in dystonia due to neurological Wilson disease, an open label placebo controlled randomized clinical trial.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Clarification submitted by Dr Jayantee Kalita Dept. Of Neurology and approved by Member Secretary for notification

**Agenda No. 42**

**IEC code:** 2022-72-DT-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Clarification submitted by Dr Narayan Prasad Dept. Of Nephrology and approved by Member Secretary for notification

**Agenda No. 43**

**IEC code:** 2022-90-IMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** To Study the Serum Metabolomic markers as predictor of Gestational Diabetes Mellitus in first trimester of pregnancy in North Indian Population: a pilot Study.

**PI:** Dr Indu Lata

**Department:** Maternal & Reprod. Health

Health

**Subject:** Clarification submitted by Dr Indu Lata Dept. Of Maternal & Reprod. Health and approved by Member Secretary for notification

**Agenda No. 44**

**IEC code:** 2022-93-EMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Investigation of mitochondrial damage associated molecular patterns as potential biomarkers for pregnancy complications

**PI:** Dr L K Sharma

**Department:** Molecular Medicine

**Subject:** Clarification submitted by Dr L K Sharma Dept. Of Molecular Medicine and approved by Member Secretary for notification

**Agenda No. 45**

**IEC code:** 2022-94-EMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Genotype-phenotype correlation with the efficacy of chelation therapy in pediatric hepatic Wilson disease in North India

**PI:** Dr Moinak Sen Sarma

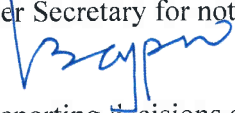
**Department:** Ped. Gastroenterology

**Subject:** Clarification submitted by Dr Moinak Sen Sarma Dept. Of Ped. Gastroenterology and approved by Member Secretary for notification

**Agenda No. 46**

**IEC code:** 2022-99-EMP-128

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** EFFECT OF ORAL SODIUM BICARBONATE ON FGF-23/KLOTHO AXIS AND BONE HEALTH IN PATIENTS WITH CHRONIC KIDNEY DISEASE.

**PI:** Dr Manas Ranjan Behera

**Department:** Nephrology

**Subject:** Clarification submitted by Dr Manas Ranjan Behera Dept. Of Nephrology and approved by Member Secretary for notification

**D. Notification for Amendments/Addendum:**

**Agenda No. 47**

**IEC code:** 2019-83-DM-109

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** An observational case control study on the safety and efficacy of Edaravone in Indian patients with Amyotrophic lateral sclerosis

**PI:** Dr Vinita E Mani

**Department:** Neurology

**Subject:** Request for two years extension of the above study.

**Committee has noted and approved.**

**Agenda No. 48**

**IEC code:** 2019-85-DM-109

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A study of the clinical, laboratory and radiological profiles, etiology and outcomes of patients with acute encephalitis syndrome to identify the uncommon causes of encephalitis in Uttar Pradesh

**PI:** Dr Vinita E Mani

**Department:** Neurology

**Subject:** Request for two years extension of the above study.

**Committee has noted and approved.**

**Agenda No. 49**

**IEC code:** 2020-196-DT-115

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Amendment report (Request for One year extension of the above study and summary of changes).

**Committee has noted and approved.**

**Agenda No. 50**

**IEC code:** 2020-196-DT-115

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** SHP669-406\_DCGI approval for protocol Amendment 3\_ IEC notification.

**Committee has noted and approved.**

**Agenda No. 51**

**IEC code:** 2020-321-EMP-EXP-33

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Mitochondrial Dynamics and Immune Response Crosstalk in Inflammatory Bowel Disease

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

**Subject:** Amendment report ((Increase the sample size from 40 to 60).

**Committee has noted and approved.**



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**E. Notification for protocol deviation:**

**Agenda No. 52**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Notification for protocol deviation (Hematocrit (HCT) value were missed due to beyond stability reason in central lab report of subject 41050100 for visit D-267, done on 04 Jul 2022 and Accidentally tapering of IP kit (10682 Exp 06/2022) without any IRT transation, however none of the study subject impacted)

**Committee has noted.**

**Agenda No. 53**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC Notification of protocol deviation (Patient No. : 41050100 and 41050266).

**Committee has noted.**

**Agenda No. 54**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Notification for protocol deviation (Patient no. : 2100009,RK)

**Committee has noted.**

**Agenda No. 55**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Notification for protocol deviation (Patient no. : 2100006 and RK).

**Committee has noted.**

**Agenda No. 56**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Notification for protocol deviation (Patient no. : 2100006 and RK).

**Committee has noted.**

**Agenda No. 57**

**IEC code:** 2021-178-DT-121

**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Type of submission:** Notification for protocol deviation

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Notification for protocol deviation (Patient no. : 2051001, ECG was missed to perform on screening visit therefore it was performed on D-75 visit dated on 5 August 2022).

**Committee has noted.**

**Agenda No. 58**

**IEC code:** 2021-178-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Notification for protocol deviation (Patient no. : 2051001, ECG was missed to perform on screening visit therefore it was performed on D-75 visit dated on 5 August 2022).

**Committee has noted.**

**Agenda No. 59**

**IEC code:** 2021-180-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC Notification of protocol deviation (Patient No. : 222402)

**Committee has noted.**

**F. General Notification:**

**Agenda No. 60**

**IEC code:** 2019-178-DT-111

**Type of submission:** General Notification

**Title of project:** Protocol I4V-MC-JAHU: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less than 18 years Old with Systemic Juvenile Idiopathic Arthritis.

**PI:** Dr Amita Aggarwal

**Department:** Clinical

Immunology

**Subject:** DCGI approval letter for JAHU protocol Amendment (d).

**Committee has noted.**

**Agenda No. 61**

**IEC code:** 2020-196-DT-115

**Type of submission:** General Notification

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** CIOMS form (Site#:009, Subject#: 406-009-0002 Onset of Event 07-Jul-2022 and Stop date of Event 14-Jul-2022).

**Committee has noted.**

**Agenda No. 62**

**IEC code:** 2020-201-EMP-115

**Type of submission:** General Notification



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** Digoxin in patients with rheumatic heart disease - a randomized placebo-controlled trial

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Study related documents (final working protocol version 1.3, dated 16th of June 2022).

**Committee has noted.**

**Agenda No. 63**

**IEC code:** 2020-329-DT-117

**Type of submission:** General Notification

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC notification of SDMC form (Dated: 10 Jun 2022)

**Committee has noted.**

**Agenda No. 64**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Study related documents for IEC notification and approval (Type of documents: IB version no. 4.0 dated 17 Dec 2020, IB version no. 5.0 dated 06 May 2022, Investigator IU dated 06 Apr 2022, Clinical Trial Agreement).

**Committee has noted.**

**Agenda No. 65**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** IEC notification for dispensing early of patient 2100001 in IRT.

**Committee has noted.**

**Agenda No. 66**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** IEC notification for listing of suspected Unexpected Serious Adverse Reactions (SUSAR) in Crizanlizumab (SEG101).

**Committee has noted.**

**Agenda No. 67**

**IEC code:** 2021-178-DT-121

**Type of submission:** General Notification

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Study related documents for IEC notification (Audio-Video ICF - Version 1.0 - Dated 01 Apr 2021, Audio-Video ICF - Version 1.0 -Dated 01 Apr 2021-translated from English to Hindi on 23 Jun 2021, Audio-Video ICF - Version 1.0 -Dated 01 Apr 2021-back translated from Hindi to English on 25 Jun 2021, Translation back translation certificate for Audio-Video form - Version 1.0 -Dated 01 Apr 2021):Hindi).

**Committee has noted.**

**G. SAE:**

**Agenda No. 68**

**IEC code:** 2020-329-DT-117

**Type of submission:** SAE reports-SGPGI

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** SAE report (Subject ID: M-41050100, report date: 30-Sep-2022, Type of SAE: Initial and Date of onset of SAE 23 Sep 2022).

**Committee has noted.**

**Agenda No. 69**

**IEC code:** 2020-329-DT-117

**Type of submission:** SAE reports-SGPGI

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** SAE report (Subject ID: M-41050100, report date: 16 Nov 2022, Type of SAE: Follow up-2 and Date of onset of SAE 23 Sep 2022).

**Committee has noted.**

**Agenda No. 70**

**IEC code:** 2020-329-DT-117

**Type of submission:** SAE reports-SGPGI

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** SAE report (Suspected Adverse Reaction (diagnosis): Death, Subject ID: M-41050100, report date: 24 Nov 2022 and Date of onset of SAE 19 Nov 2022).

**Committee has noted.**

**Agenda No. 71**

**IEC code:** 2020-329-DT-117

**Type of submission:** SAE reports-SGPGI

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** SAE report (Suspected Adverse Reaction (diagnosis): Death, Subject ID: M-41050100, report date: 05 Dec 2022 and Date of onset of SAE 19 Nov 2022).



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

**Committee has noted.**

**Agenda No. 72**

**IEC code:** 2020-329-DT-117

**Type of submission:** SAE reports-SGPGI

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** SAE report (Subject ID: M-41050100, report date: 13-Oct-2022, Type of SAE: Follow up 1 and Date of onset of SAE 23 Sep 2022).

**Committee has noted.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 73**

**IEC code:** 2017-47-DT-96

**Type of submission:** Final/Annual/Progress reports

**Title of project:** Investigation of Rheumatic AF Treatment Using vitamin K antagonists, rivaroxaban or aspirin Studies. (INVICTUS)

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Annual Progress report (Reporting date: 05-09-2022).

**Committee has noted.**

**Agenda No. 74**

**IEC code:** 2020-196-DT-115

**Type of submission:** Final/Annual/Progress reports

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Annual Progress report (Reporting date: 10.11.2022).

**Committee has noted.**

**Agenda No. 75**

**IEC code:** 2020-286-DT-116

**Type of submission:** Final/Annual/Progress reports

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Annual Progress report (Reporting date: 14.06.2022).

**Committee has noted.**

**Agenda No. 76**

**IEC code:** 2018-185-MCh-EXP-4

**Type of submission:** Study Close out Notification

**Title of project:** PROSPECTIVE CASE CONTROL STUDY OF OBJECTIVE CARDIAC AND VASCULAR CHANGES IN PHEOCHROMOCYTOMA AND PARAGANGLIOMA AND THEIR REVERSAL FOLLOWING CURATIVE SURGERY

**PI:** Dr Roopali Khanna

**Department:** Cardiology


**Subject:** Study completion report (Date of termination: 31.08.2022).

**Committee has noted.**

**Agenda No. 77**

**IEC code:** 2019-35-EMP-108

**Type of submission:** Study Close-out Notification

  
**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Title of project:** Host Determinants of Hepatitis E Disease Severity  
**PI:** Dr Amit Goel **Department:** Gastroenterology  
**Subject:** Study completion report (Date of termination: 30th June 2022).  
**Committee has noted.**

**Agenda No. 78** **IEC code:** 2019-67-EMP-108  
**Type of submission:** Study Close out Notification  
**Title of project:** Clinical Trial of the Content -based Image Retrieval-based Computer Aided Diagnosis (CBIR-CAD) for lung nodules and ILD patterns  
**PI:** Dr Sunil Kumar **Department:** Radiodiagnosis  
**Subject:** Premature termination report (Reporting date: 01-09-2022).  
**Committee has noted.**

**Agenda No. 79** **IEC code:** 2020-216-DT-115  
**Type of submission:** Study Close out Notification  
**Title of project:** Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD)  
**PI:** Dr Alok Nath **Department:** Pulmonary Medicine  
**Subject:** Premature termination report (Date of termination: 31 Oct 2022).  
**Committee has noted.**

**Agenda No. 80** **IEC code:** 2020-66-DM-EXP-15  
**Type of submission:** Study Close out Notification  
**Title of project:** Macrophage migration inhibitor factor, its receptor CD74 and antibodies to anti CD74 in ERA category of JIA  
**PI:** Dr Amita Aggarwal **Department:** Clinical Immunology  
**Subject:** Study completion report (Date of termination: May 2022).  
**Committee has noted.**

**Agenda No. 81** **IEC code:** 2021-30-DM-EXP-36  
**Type of submission:** Study Close out Notification  
**Title of project:** Infections in Systemic Lupus erythematosus :A retrospective study  
**PI:** Dr Amita Aggarwal **Department:** Clinical Immunology  
**Subject:** Study completion report (Date of termination: Aug 2022).  
**Committee has noted.**



(Dr. Durga P. Misra)  
Member Secretary,  
IEC, SGPGI



(Dr. M.K. Mitra)  
Chairman,  
IEC, SGPGI



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



**Lt Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow

## SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Minutes of the 125<sup>th</sup> Institutional Ethics Committee meeting held on 01<sup>st</sup> April, 2022 at 10.00 AM in the committee room of the Guest house, SGPGIMS, Lucknow.

### **Present:**

- |  |                  |
|--|------------------|
| 1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow        | Chairman         |
| 2. Prof. Aneesh Srivastava, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow      | Member           |
| 3. Justice S.C Verma, <i>Retd.</i> High Court Judge Allahabad -  | Member           |
| 4. Shri. Vijai Varma, Former District Judge & Chairman Upphokta Forum, Lucknow                           | Member           |
| 5. Shri. Sharat Pradhan, Senior Journalist, (B-4, Dilkusha Colony, Lucknow                               | Member           |
| 6. Dr. Mohan Gurjar, Additional Professor, Department of CCM, S G P G I M S, Lucknow                     | Member           |
| 7. Prof. M. K. Mitra Former HOD Medicine, KGMU, Lucknow  | Member           |
| 8. Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow  | Member           |
| 9. Prof. V.L Bhatia, Prof. Department of Endocrinology, S G P G I M S, Lucknow                           | Member           |
| 10. Prof. A.K Srivastava, <i>Retd.</i> Prof. Department of Sociology, University of Lucknow              | Member           |
| 11. Dr. Gautam Palit, Ex-Head, Div. of Pharmacology & Seni. Dep. Dir. & Medical Officer, CSIR-CDRI, Lko. | Member           |
| 12. Dr. S. Srivastava, <i>Retd.</i> Scientist-IV, Research Cell, S G P G I M S, Lucknow                  | Member           |
| 13. Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P G I M S, Lucknow                          | Member Secretary |

Members Mrs Shalini Mathur and Dr Manuka Khanna, could not attend the meeting due to other commitments. Dr Manuka Khanna had sent her comments on the projects allotted.

**Determination of quorum:** quorum was complete: 13 members present, with 9 non-institutional members.

### **A: General discussions and confirmation of Minutes:**

The Chairman, Dr Chandishwar Nath, welcomed all members. Dean Prof Aneesh Srivastava also greeted all members. All members expressed their happiness in able to meet physically after a period of more than two years in which only online meetings were held. Director, Prof RK Dhinan, who was invited to hand over the certificate of NABH accreditation of the IEC, SGPGIMS, to the Chairman, IEC and all members, praised the efforts of the IEC. He congratulated the Chairman, Member Secretary, all IEC members and staff of Bioethics Cell in accomplishing this feat and maintaining the high ethical standards. Dr Chandishwar Nath said that IEC of SGPGI is one of the best in the country and should take a lead in educating other regional IEC's in various centers and remembered earlier Chairman Late Prof BN Dhawan for his great contribution towards development of IEC-SGPGI. The staff of the Bioethics cell, including Senior Adm. Officer, Mr. Anand Srivastava, Data entry operator, Mr. Ashfaq Ulla Khan and attendant, Mr. Raju Srivastava were handed over a potted plant by the Director, Chairman and Member Secretary.

Member Secretary, Prof Vinita Agrawal, informed that email has been received from FERCI that FERCAP re-survey of IEC, SGPGI is due in 2022 and can be held in April 2022 or in June 2022. It is not clear whether it be held online/offline. The matter was discussed amongst all members. The members were of the view that our IEC is NABH accredited and also registered with DCGI and DHR. There is no definite academic/scientific benefit from FERCAP accreditation.

Moreover, it will involve payments of fees etc. amounting to USD 3700. If the survey is held offline, the Institute would have to take care of TA, DA etc. of survey coordinator, lead surveyor and all surveyors. After detailed discussions and deliberations, it was decided that FERCAP survey may not have any added advantage for the IEC and the Institute.

Member Secretary reported and informed the IEC, about the decisions of the SAE subcommittee for compensation in the clinical trial from the Department of Cardiology (subject ID 0090058 (J-D) under the clinical trial, IEC Code 2017-47-DT-96).

**Disclosure of conflict of interest:** Chairman, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting.

The following member did not participate in the deliberations of the following agenda and was out of the committee room during the discussions:

- Dr Vinita Agrawal, PI for the agenda no. 7 (2022-32-IMP-125)
- Dr Mohan Gurjar, Co-PI for the agenda no. 25 (2021-305-IMP-EXP-44)

**Reading and approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 124<sup>th</sup> IEC meeting held on 29<sup>th</sup> January, 2022. All members approved the minutes.

## **B. Review of New Proposals:**

### **Agenda No. 1**

**IEC code:** 2022-14-IMP-125

**Type of submission:** Project Intramural

**Title of project:** Evaluation of techniques and outcome of Celiac Plexus Neurolysis by fluoroscopy, CT and Robot assisted CT guidance: Randomized comparative, Parallel trial

**PI:** Dr. Chetna Shamshery

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Inform about competency of the investigators for the robotic procedures.
2. All patients may not be able to pay for the robotic procedure. How will the investigators randomize participants in the groups?
3. Clearly mention about complications and how they will be managed?

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 2****IEC code:** 2022-17-IMP-125**Type of submission:** Project Intramural**Title of project:** Redefining 'triple negative myeloproliferative neoplasm' using targeted next generation sequencing**PI:** Dr Khaliqur Rahman**Department:** Clinical Hematology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

The committee has given the following suggestions to the PI:

1. The study has a retrospective and prospective arm. Mention the essentiality of the retrospective arm.
2. For the prospective study, informed consent documents are required. Mention the inclusion and exclusion criteria.
3. For the retrospective arm, kindly inform about the consent to use the stored samples for genetic analysis. Ensure that the samples are anonymized with delinking of identity with the stored samples.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 3****IEC code:** 2022-18-IMP-125**Type of submission:** Project Intramural**Title of project:** New Xpert MTB/XDR assay : a prospective single centre pilot study**PI:** Dr Richa Mishra**Department:** Microbiology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and issues related to informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The project is incomplete with no information about study design and methodology.
2. There is no information about participant inclusion and exclusion criteria.
3. The informed consent documents are not submitted.
4. There is no case proforma.

**Decision:** Rejected.

PI advised to resubmit the project.

**Agenda No. 4****IEC code:** 2022-20-IMP-125**Type of submission:** Project Intramural**Title of project:** Role of betablocker and norepinephrine in the outcome of stroke.**PI:** Dr Jayantee Kalita**Department:** Neurology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention the method of randomization in the two groups. Grouping should be clearly defined (Metoprolol vs amlodipine)
2. Submit child information document and assent form for participants aged 15-18years.
3. Submit proper bilingual information documents for LAR/parents.
4. Get CTRI before start of the study.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 5**

**IEC code:** 2022-26-IMP-125

**Type of submission:** Project Intramural

**Title of project:** Status of BRCA gene in breast cancer

**PI:** Dr Sushila Jaiswal

**Department:** Pathology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clearly mention the retrospective and prospective part of the study.
2. Mention the time of blood collection.
3. Clarify the sample size; mentioned variably as 40 and 30 in the documents.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 6**

**IEC code:** 2022-28-IMP-125

**Type of submission:** Project Intramural

**Title of project:** Can we improve detection of occult neurological changes in patients with hepatic Wilson disease?

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention in the participant information document (PID) that the standard of care will be given/remain and also about repeat MRI and MRS.
2. Justify the inclusion of controls. Is it ethical to perform MRS and MRI in non-

- Wilson children? Can the investigators get data from historical references/data from literature?
3. It is a suggestion to change in title of the study to 'Can we improve management of hepatic Wilson disease by early detection of neurological changes?' The PI may like to consider and decide.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 7**

**IEC code:** 2022-32-IMP-125

**Type of submission:** Project Intramural

**Title of project:** Next-Generation Sequencing for Genetic testing in Early-onset Steroid-resistant FSGS and Correlation with Ultrastructural Features

**PI:** Dr Vinita Agrawal

**Department:** Pathology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

**Decision:** Approved.

**Agenda No. 8**

**IEC code:** 2021-313-EMP-125

**Type of submission:** Project Extramural

**Title of project:** Micro-particles generated from SARS-CoV-2 syncytia and phosphatidylserine exposure as a pro-coagulant factor during COVID-19 blood coagulation

**PI:** Dr Santosh Kumar Verma

**Department:** Molecular Medicine

Primary reviewer (Technical/PID & CF): Dr Surendra Srivastava

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify about frequency of blood collection and mention in the participant information document (PID).
2. The PID should be comprehensive.
3. Check exclusion criteria for controls. It is mentioned that participants free of infection and hypertension would be excluded.
4. Submit a copy of approval letter from the funding agency to the IEC.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 9****IEC code:** 2021-337-EMP-125**Type of submission:** Project Extramural**Title of project:** Role of Emerging SARS-CoV-2 variants in reshaping of serological responses of COVID-19 recovered patients and in vaccinated individuals: Study in North Indian Population**PI:** Dr Santosh Kumar Verma**Department:** Molecular Medicine

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. As Northern Indian is a vast area, so P.I. should identify which state they are covering.
2. The PID mentions that study is prospective but also mention about pre-pandemic period. Kindly correct.
3. Check exclusion criteria for controls. It is mentioned that participants free of infection and hypertension would be excluded.
4. Mention the role of collaborator. Submit IEC clearance from the collaborating center.
5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 10****IEC code:** 2022-11-EMP-125**Type of submission:** Project Extramural**Title of project:** Role of small intestinal bacterial overgrowth in pathogenesis of functional dyspepsia: a case control study**PI:** Dr Ujjala Ghoshal**Department:** Microbiology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Justify the inclusion of controls in the study. Clarify if gut aspirates will be taken in controls? Give inclusion and exclusion criteria for controls.
2. Suggestion to include controls later as per the results of the study.
3. Submit a copy of approval letter from the funding agency to the IEC.
4. Mention about the side effects of the drug Rifaximin in the participant information document (PID).

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.



**Agenda No. 11****IEC code:** 2022-13-EMP-125**Type of submission:** Project Extramural**Title of project:** A pilot prospective cohort study for assessing maternal mitochondrial DNA copy number variations during pregnancy as a potential biomarker for predicting healthy or complicated pregnancy**PI:** Dr L K Sharma**Department:** Molecular Medicine

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The study design would require changes as the PI cannot determine at the time of recruitment if the participant will be a case/control. All pregnancies can be followed to see who develops pre-eclampsia.
2. Clarify the amount of blood to be collected.
3. Submit comprehensive and proper participant information document (PID).
4. Since only participants with pre-eclampsia are to be included as a complication; change the title of the study to 'A pilot..... predicting pre-eclampsia'.
5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 12****IEC code:** 2022-10-DM-125**Type of submission:** Project DM/MCh/MD**Title of project:** A Prospective Interventional Pilot study evaluating the Safety and Efficacy of Endoscopic Ultrasound guided Liver Biopsy in coagulopathy patients**PI:** Dr Praveer Rai**Department:** Gastroenterology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

- Submit proper Hindi participant information document (PID). Follow-up is mentioned as 'पीछा करेंगे'।

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 13****IEC code:** 2022-29-DM-125

**Type of submission:** Project DM/MCh/MD

**Title of project:** A Prospective, Interventional, Pilot study evaluating the Efficacy of EUS guided Liver Biopsy (EUS-LB) in Indeterminate Hepatic Solid Masses (HSM)

**PI:** Dr Samir Mohindra

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Pt. 14 of participant information document (PID): it is mentioned that the risk is moderate to high. Clarify the increase in risk as compared to conventional procedures. Also give an account about information about the risk involved from the available literature.
2. Pt. 14 of participant information document (PID): mention that the standard of care would be provided free of cost.
3. Submit proper Hindi PID.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 14**

**IEC code:** 2021-330-IP-125

**Type of submission:** Project Independent

**Title of project:** Evaluation of the effects of skin lifting using loop adhesion method on Internal Jugular Vein (IJV) dimensions and ease of cannulation. Prospective, randomized, single blinded controlled trial.

**PI:** Dr Devendra Gupta

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Give a reference for the procedure of the new technique being studied.
2. Participant information document (PID) mentions about brain tumors, while methodology mentions about all surgical patients. Clarify.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 15**

**IEC code:** 2022-12-IP-125

**Type of submission:** Project Independent

**Title of project:** Evaluation of circulating Vascular Endothelial Growth Factors (VEGF), endothelial and platelet microparticles in orbital lymphaticovenous malformations in Indian patients.

**PI:** Dr Rachna Agarwal

**Department:** Ophthalmology

Primary reviewer (Technical/PID & CF): Dr Surendra Srivastava

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify if only children will be included in the study.
2. Submit proper participant information document (PID) for participants (controls and patients).
3. Submit proper consent forms as per IEC SOPs.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 16**

**IEC code:** 2022-16-IP-125

**Type of submission:** Project Independent

**Title of project:** Comparison of IVC distensibility guided goal directed fluid therapy with conventional fluid therapy in renal transplant recipients- A prospective, randomized controlled trial

**PI:** Dr Tapas Kumar Singh

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

**Decision** Approved.

**Agenda No. 17**

**IEC code:** 2022-15-DT-125

**Type of submission:** Project Drug/device trials

**Title of project:** Prophylaxis for patients at risk of COVID-19 infection (PROTECT).

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Dr. Manuka Khanna

Primary reviewer Legal: Justice S.C Verma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The name of SGPGI is not present in the list of approved centers by DCGI and in CTRI.
2. Submit Insurance certificate.
3. Submit CTA.
4. English PID, point no. 7-begins with the phrase "Niclosamide is not licensed in this formulation"; it may be better explained as "Niclosamide is a licensed medicine in the form of a tablet, but not in the form of a nasal spray".
5. In the Hindi PID, in point 7, the sentence: इस परीक्षण.....पर हलके लक्षणों को ठीक

कर सकता है निसर्गेशनमल है", is not a proper translation of the English sentence, and gives the impression "if used in a proper way, side effects are minimized" which was not stated in the English version. Kindly check and correct.

**Decision:** Major Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 18**

**IEC code:** 2022-23-DT-125

**Type of submission:** Project Drug/device trials

**Title of project:** A Multicentric, Post Marketing, Observational Study to Determine the impact of IVABID® OD on average Resting Heart Rate in patients with reduced ejection fraction with systolic dysfunction.

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr A K Srivastava

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. CTA, pg. 127 clause 13: delete point (d).
2. CTA, clause 23: mention that the seat of arbitration will be Lucknow.
3. Insurance policy mentions, retroactive date as 1<sup>st</sup> January 1977. What is the relevance of this date?

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 19**

**IEC code:** 2022-24-DT-125

**Type of submission:** Project Drug/device trials

**Title of project:** Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Efficacy and Safety of LIB003 in Patients With Cardiovascular Disease, or at High Risk for Cardiovascular Disease, on Stable Lipid-Lowering Therapy Requiring Additional

**PI:** Dr Aditya Kapoor

**Department:** Cardiology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Dr. Manuka Khanna

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The PI is requested, not to submit the self-signed certificate of approval as Head of the Department.

2. Will blood/DNA be sent abroad? If yes, submit HMSC clearance and material transfer agreement.
3. CTA clause 3.5: should be deleted.
4. Sponsor should be arrayed as a party of the CTA and signatory.
5. CTA, pg. 383, point 15: under 'Assignment and delegation'-notice should be given to the Institute.
6. CTA, pg 383, point 12: point 12.1 should be deleted.
7. CTA: There is no clause for dispute resolution. Mention the clause and state that the jurisdiction will be in Courts of Lucknow.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 20**

**IEC code:** 2022-25-DT-125

**Type of submission:** Project Drug/device trials

**Title of project:** A streamlined, multicentre, randomized, parallel group, double-blind placebo-controlled superiority trial to evaluate the effect of EMPAgliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Dr A K Srivastava

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The name of SGPGI is not present in the list of approved centers by DCGI and in CTRI.
2. CTA mentions about 15 years retention period by the Institute. Clarify. There are no guidelines for the budget/space in the Institute. Contact Research cell.
3. CTA, under 'Assignment and delegation'-notice should be given to the Institute.
4. CTA: the jurisdiction should be in the Courts of Lucknow and not Mumbai.

**Decision:** Major Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee:**

**The recommendation of the Member Secretary/3-Member Committee/Expedite Review Committee (EXP meeting no. 44, agenda 21-36) who has given clearance for the proposals has been approved by the committee.**

**Agenda No. 21**

**IEC code:** 2021-291-IMP-EXP-44

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** STANDARDIZATION OF REAL-TIME PCR ON BLOOD AND BAL FOR IMPROVING THE DIAGNOSIS OF INVASIVE PULMONARY ASPERGILLOSIS  
**PI:** Dr Zia Hasim **Department:** Pulmonary Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 22** **IEC code:** 2021-293-IMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** A pilot study on the prevalence of Cardiac Sarcoidosis among the patients of Systemic Sarcoidosis by speckled tracing echocardiography, cardiac MRI and FDG PET-CT.  
**PI:** Dr Alok Nath **Department:** Pulmonary Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 23** **IEC code:** 2021-298-IMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** ANCA Associated vasculitis diagnosis, management and risks amidst the COVID-19 pandemic  
**PI:** Dr Vikas Agarwal **Department:** Clinical Immunology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 24** **IEC code:** 2021-299-IMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Reactive arthritis Knowledge and perceptions changes amidst the COVID-19 pandemic  
**PI:** Dr Vikas Agarwal **Department:** Clinical Immunology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 25** **IEC code:** 2021-305-EMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** CMV reactivation in mechanically ventilated patients and its impact on clinical outcome.  
**PI:** Dr Atul Garg **Department:** Microbiology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 26** **IEC code:** 2021-306-EMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Investigation of mitochondrial quality control and mitochondrial modulation for targeting of glioma initiating cells: a potential therapeutic approach for glioblastoma  
**PI:** Dr L K Sharma **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 27** **IEC code:** 2021-307-SRA-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** TARGETING OF GLIOMA INITIATING CELLS VIA AUTOPHAGY MODULATION FOR THERAPEUTIC INTERVENTIONS IN GLIOMA  
**PI:** Dr L K Sharma **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 28** **IEC code:** 2021-309-EMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Renal transcriptome regulation in kidney disease  
**PI:** Dr Swasti Tiwari **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 29** **IEC code:** 2021-315-SRF-EXP-44

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Circulating Microparticles and Monocyte Activation in Renal Antibody Mediated Allograft Rejection  
**PI:** Dr Vinita Agrawal **Department:** Pathology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 30** **IEC code:** 2021-317-EMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Serum profile of bile acids and lipids to identify the putative pruritogenic agent in patients with cholestasis  
**PI:** Dr Amit Goel **Department:** Gastroenterology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 31** **IEC code:** 2021-319-SRA-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Role of novel microRNAs in the patho-mechanism of early kidney disease  
**PI:** Dr Swasti Tiwari **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 32** **IEC code:** 2021-320-IMP-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Diagnostic performance of hepatitis C virus core antigen (HCVcAg) test in patients with cirrhosis  
**PI:** Dr Amit Goel **Department:** Gastroenterology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 33** **IEC code:** 2021-321-SRF-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Investigation of mitochondrial modulation for therapeutic targeting in Triple Negative Breast Cancers(TNBCs)  
**PI:** Dr L K Sharma **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 34** **IEC code:** 2021-322-SRF-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Targeting metastatic potential through regulating mitochondria in Colorectal cancer  
**PI:** Dr L K Sharma **Department:** Molecular Medicine  
**Subject:** Expedite review project for IEC notification

**Agenda No. 35** **IEC code:** 2021-338-SRF-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Stimulatory effects of circulating microvesicles on Monocytic cell lineage in IgAN  
**PI:** Dr Vinita Agrawal **Department:** Pathology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 36** **IEC code:** 2021-339-PDCC-EXP-44  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Cytogenetic microarray in neurodevelopmental disorders- utility of reanalysis of data  
**PI:** Dr Shubha Phadke **Department:** Medical Genetics  
**Subject:** Expedite review project for IEC notification

#### **D. Notification for Amendments/Addendum:**

**Agenda No. 37** **IEC code:** 2018-138-IP-106  
**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Efficacy and safety of exercise in mild to moderate myasthenia gravis: an open labeled controlled trial. [Rest Or Exercise in Myasthenia Gravis (RESTOREX MG)].

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Amendment Report (Sample size 46, the low dose or high dose steroid better disease control and additional immunosuppression is better than steroid alone and efficacy of plasmapheresis over IVIG).

**Committee has noted.**

**Agenda No. 38**

**IEC code:** 2018-185-MCh-EXP-4

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** PROSPECTIVE CASE CONTROL STUDY OF OBJECTIVE CARDIAC AND VASCULAR CHANGES IN PHEOCHROMOCYTOMA AND PARAGANGLIOMA AND THEIR REVERSAL FOLLOWING CURATIVE SURGERY

**PI:** Dr Roopali Khanna

**Department:** Cardiology

**Subject:** Amendment Report (07.02.2022).

**Committee has noted.**

**Agenda No. 39**

**IEC code:** 2019-162-EMP-111

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Development of blood and urine based biomarker for early diagnosis of clear cell renal cell carcinoma patients and identification of therapeutic target for the disease

**PI:** Dr Naveen Kumar Gautam

**Department:** Urology

**Subject:** Amendment Report (Adding a new Co-PI, Dr. Somendu Roy, Sr. Scientist, CSIR-IITR, Lucknow).

**Committee has noted. Submit CV of collaborator and IEC clearance from the collaborating Institute.**

**Agenda No. 40**

**IEC code:** 2019-164-EMP-111

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Study on Polio and Non-Polio enterovirus infections in children with immunodeficiency at multiple medical institutes across India

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Amendment Report (2 Year extension for entering Phase II of the study and study will include 13 more centres across India, Study will continue following the same protocol).

**Committee has noted and approved.**

**Agenda No. 41**

**IEC code:** 2019-178-DT-111

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Protocol I4V-MC-JAHU: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less than 18 Years Old with Systemic Juvenile Idiopathic Arthritis.

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Amendment and study related documents.

**Committee has noted.**

**Agenda No. 42**

**IEC code:** 2019-47-EMP-108

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Understanding pathogenesis of Takayasu arteritis – transcriptomics applied to peripheral blood mononuclear cells (PBMC) and involved vessels, and the role of various T-cell subsets.

**PI:** Dr Durga Prasanna Misra

**Department:** Clinical Immunology

**Subject:** Amendment Report (PI Planned to do T cell profile, cytokines and transcriptomics on patient's peripheral blood. To complete the picture of inflammatory milieu, study shall be evaluating



endothelial, platelet and leucocyte microparticles in already collected plasma samples. No further samples are to be taken from patients).

**Committee has noted and approved.**

**Agenda No. 43**

**IEC code:** 2021-143-IP-EXP-39

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Patient reported outcomes of COVID-19/COVID-19 vaccine in patients with rheumatic diseases

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

**Subject:** Amendment Report (Survey has been revised to include questions on booster dose, Survey would be translated into other languages and Dr Latika Gupta would be an external Co-PI).

**Committee has noted. Submit the CV and present affiliation of the external co-PI.**

**Agenda No. 44**

**IEC code:** 2021-180-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neuro Ophthalmology

**Subject:** Study related documents for IEC notification (ICF version 3.0 dated 03 Jan 2022).

**Committee has noted.**

**E. Notification for protocol deviation:**

**Agenda No. 45**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Protocol deviation (Patient No. and Name: 41050093 Initial H-B, 41050100 Initial M- and 41050118 Initial K--).

**Committee has noted.**

**F. General Notification:**

**Agenda No. 46**

**IEC code:** 2019-124-DT-109

**Type of submission:** General Notification

**Title of project:** A Phase 3 Randomized, Open Label (Sponsor - Blind), active - controlled, parallel group, multi-centre, event driven study in non -dialysis subjects with anemia associated with chronic kidney disease to evaluate the Safety and efficacy of Daprodustat compar

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification CSR Report

**Committee has noted.**

**Agenda No. 47**

**IEC code:** 2019-178-DT-111

**Type of submission:** General Notification

**Title of project:** Protocol I4V-MC-JAHU: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less than 18 Years Old with Systemic Juvenile Idiopathic Arthritis.

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Study related documents for IEC notification.

**Committee has noted.**

**Agenda No. 48**

**IEC code:** 2019-208-DT-113

**Type of submission:** General Notification

**Title of project:** " Protocol I4V-MC-JAHV: A Randomized, Double-Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 2 Year to Less Than 18 Years old with Juvenile Idiopathic Arthritis"

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Discontinuation report dated 13 Feb 2022.

**Committee has noted.**

**Agenda No. 49**

**IEC code:** 2020-196-DT-115

**Type of submission:** General Notification

**Title of project:** SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Study related documents for IEC notification (CTRI No: CTRI /2021/07/034906 dated 15 Jul 2021, CTA; Fully executed CTA Signed dated 29 Nov 2021, Insurance Certificate No. : P0422200001/9999/100163, valid from 15 Jun 2021 to 14 Jun 2022 and Source document Template for Screening and Baseline Visit, All Visits Study Completion or early Termination Visit: Version 1.0 dated 21 Jul 2021).

**Committee has noted.**

**Agenda No. 50**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Study related documents for IEC notification ( Updated CTRI registration :CTRI/2020/10028544 Registered on: 22/10/2020).

**Committee has noted.**

**Agenda No. 51**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical Hematology

**Subject:** Study related documents for IEC notification (Updated Insurance Certificate Policy No. : P0422200001/9999/100188).

**Committee has noted.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 52**

**IEC code:** 2019-192-IMP-113

**Type of submission:** Final/Annual/Progress reports

**Title of project:** Cytomegalovirus reactivation in critically ill immunocompetent patients with septic shock.

**PI:** Dr Atul Garg

**Department:** Microbiology

**Subject:** Annual Progress report dated 08.02.2022 and request for extension).

**Committee has noted.**

**Agenda No. 53**

**IEC code:** 2020-329-DT-117

**Type of submission:** Final/Annual/Progress reports

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Annual Progress report dated 20.01.2022.  
**Committee has noted.**

**Agenda No. 54**

**IEC code:** 2018-176-IP-107

**Type of submission:** Study Close out Notification

**Title of project:** Use of a short course of low-dose Pregabalin for the treatment of Restless Leg Syndrome (RLS) in patients with chronic liver disease

**PI:** Dr Amit Goel

**Department:** Gastroenterology

**Subject:** Study Completion report dated 26.02.2022.

**Committee has noted.**

**Agenda No. 55**

**IEC code:** 2018-60-IMP-103

**Type of submission:** Study Close out Notification

**Title of project:** Assessment of selenium deficiency in gluten-free diet in patients with celiac disease

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

**Subject:** Study Completion report dated 18.01.2022.

**Committee has noted.**

**Agenda No. 56**

**IEC code:** 2019-60-DM-EXP-7

**Type of submission:** Study Close out Notification

**Title of project:** Utility of follow-up endoscopy/imaging to document healing/resolution in pediatric abdominal tuberculosis

**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

**Subject:** Study Completion report (Date of Termination: 20 Jan 2022).

**Committee has noted.**

**Agenda No. 57**

**IEC code:** 2020-259-IP-EXP-29

**Type of submission:** Study Close out Notification

**Title of project:** Achalasia cardia in children: clinical profile, subtypes on high resolution oesophageal manometry and response to therapy

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Study Completion report (Date of Termination: Sep 2021).

**Committee has noted.**

Dr. Col Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

(Dr. Vinita Agrawal)  
Member Secretary,  
IEC, SGPGI

(Dr. Chandishwar Nath)  
Chairman,  
IEC, SGPGI

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 126<sup>th</sup> Institutional Ethics Committee** meeting held on Saturday, 21<sup>st</sup> May 2022, at 10.30 am, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

**Present:**

1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
2. Prof. Aneesh Srivastava, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Member
3. Justice S.C Verma, <i>Retd.</i> High Court Judge Allahabad -	Member
4. Shri. Vijai Varma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
5. Shri. Sharat Pradhan, Senior Journalist, (B-4, Dilkusha Colony, Lucknow	Member
6. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
7. Dr. Mohan Gurjar, Additional Professor, Department of CCM, S G P G I M S, Lucknow	Member
8. Prof. M. K. Mitra Former HOD Medicine, KGMU, Lucknow	Member
9. Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow	Member
10. Prof. V.L Bhatia, Prof. Department of Endocrinology, S G P G I M S, Lucknow	Member
11. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
12. Prof. A.K Srivastava, <i>Retd.</i> Prof. Department of Sociology, University of Lucknow	Member
13. Dr. Gautam Palit, Ex-Head, Div. of Pharmacology & Seni. Dep. Dir. & Medical Officer, CSIR-CDRI, Lko.	Member
14. Dr. S. Srivastava, <i>Retd.</i> Scientist-IV, Research Cell, S G P G I M S, Lucknow	Member
15. Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P G I M S, Lucknow	Member Secretary

Members Dr Aneesh Srivastava, Justice SC Verma, Dr Amita Panday, Dr Gautam Palit and Dr Surendra Srivastava could not attend the meeting due to other commitments.

**Determination of quorum:** quorum was complete: 10 members present, with 7 non-institutional members.

**A: General discussions and confirmation of Minutes:**

The Chairman, Dr Chandishwar Nath, welcomed all members. Member Secretary, Dr Vinita Agrawal, proposed to conduct a CME on behalf of the IEC, tentatively in October 2022. All members agreed and the Chairman suggested that a tentative program can be made and circulated by email for inputs and suggestions. Dr Mohan Gurjar suggested that along with CME, a GCP workshop can also be conducted.

**Disclosure of conflict of interest:** Chairman, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting.

None of the members declared any conflict of interest.

**Reading and approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 125<sup>th</sup> IEC meeting held on 1<sup>st</sup> April, 2022. All members approved the minutes.

## **B. Review of New Proposals:**

### **Agenda No. 1**

**IEC code:** 2022-18-IMP-125

**Type of submission:** Project Intramural

**Title of project:** New Xpert MTB/XDR assay : a prospective single centre pilot study

**PI:** Dr Richa Mishra

**Department:** Microbiology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

This was a resubmission of the project which was rejected by the committee in the previous meeting due to incomplete submission.

Scientific issues and ethical issues were discussed.

**Decision** Approved. Waiver of consent granted.

### **Agenda No. 2**

**IEC code:** 2022-66-IMP-126

**Type of submission:** Project Intramural

**Title of project:** Anti fibrotic effect of tadalafil in liver fibrosis: an in vitro and in vivo study

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues and ethical issues were discussed.

The committee has given the following suggestions to the PI:

1. Mention the years from which archival blocks from the Department of Pathology will be identified and included in the study.
2. Confirm that the consent is taken/full confidentiality maintained for the previously collected liver specimens (n=8).

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

### **Agenda No. 3**

**IEC code:** 2022-38-EMP-126

**Type of submission:** Project Extramural

**Title of project:** Evaluating Molecular portraits of pituitary tumour: relevance for pathogenesis and its clinical significance

**PI:** Dr Sushila Jaiswal

**Department:** Pathology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention the role of collaborator. If human samples are being handled in the collaborator's

- institution, then ethical clearance document from that center should be submitted.
2. Submit waiver of consent document.
  3. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 4**

**IEC code:** 2022-52-EMP-126

**Type of submission:** Project Extramural

**Title of project:** Technical feasibility and efficacy of upper gut aspiration and culture using a double-lumen catheter in comparison with hydrogen breath tests among patients suspected having small intestinal bacterial overgrowth

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention the source of funds for the study. The patients should not bear any 'extra cost' for the study.
2. The references quoted for the use of double lumen catheter are from the PI on the same condition (SIBO). Kindly mention the what is new in the present study?
3. Hindi PID, point 3: has translated 'culture' to 'sanskriti'. Please check and correct.
4. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.
5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 5**

**IEC code:** 2022-54-EMP-126

**Type of submission:** Project Extramural

**Title of project:** Aptamer based diagnostic device development for detecting Hepatitis-C virus (HCV) and HCV core Antigen

**PI:** Dr Amit Goel

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issue and ethical issues were discussed.

The committee has given the following suggestions to the PI:

1. If human samples are being handled in the collaborator's institution, then ethical clearance document from that center should be submitted.
2. Methodology p23; "In the present work, the proposed Hepatitis C Viral particle and HCV core antigen test will be first performed separately for around 100 serum samples provided by Dr. Amit Goel in SGPGI, Lucknow. The sensitivity and specificity values will be noted. Thereafter tests will be performed on the combined lateral flow assay for the same 100 samples." Project submission form mentions 10 samples. Clarify about the number of samples.
3. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 6**

**IEC code:** 2022-58-EMP-126

**Type of submission:** Project Extramural

**Title of project:** Knowledge, attitude and practice (KAP) survey of low fermentable oligo-, di-, mono-saccharide and polyol (FODMAP) diet awareness among Indian gastroenterologists and physicians

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

- PI should include a statement "I have understood the study and my participation is voluntary" in the beginning of survey form.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 7**

**IEC code:** 2022-61-EMP-126

**Type of submission:** Project Extramural

**Title of project:** The effect of HPV infection on pregnancy on maternal and neonatal outcome.

**PI:** Dr Amrit Gupta

**Department:** Maternal & Reprod. Health

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Control group should be defined very clearly. It is mentioned as 'Non-pregnant' in PID while in timelines 2nd year it seems that they are non-HPV pregnant women. It is stated "All data will be recorded for comparative analysis in these two groups" but groups are not defined.
2. Clearly mention exclusion and inclusion criteria for both groups.
3. Kindly correct the PIDs.
  - a. English PIDs (Both p22 & 29) are for control as per title and invite non-pregnant participant as per para 2 but also mentions to collect samples of placental tissues and cord blood at the delivery.
  - b. Hindi PIDs (Both p24 & 31) are for pregnant women as per title and description.
  - c. English and Hindi PIDs para 3 . The statement "You should definitely participate in this research study because you are an Indian citizen" is irrelevant for the study and should be removed.
  - d. There is a statement that study is being conducted 'central Govt. employees. How is this relevant for the study?
4. Submit a copy of approval letter from the funding agency to the IEC.

**Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 8**

**IEC code: 2022-71-PhD-126**

**Type of submission:** Project PhD

**Title of project:** Complex omics signatures for different stages of ARDS and translation strategies for improved clinical management

**PI:** Dr Afzal Azim

**Department:** Critical Care Medicine

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Human samples are being handled in the collaborator's institution; ethical clearance from that center should be submitted.
2. Mention the amount of sample collection. Also mention the details of sample collection in the PID.
3. Mention the source of funding.
4. PID: Point 4 mentions: 'Why have I been chosen? On the basis of your clinical features and investigations you have been diagnosed with ARDS. For the characterization of ARDS we will use blood serum which will be removed as part of your treatment.' The same has been mentioned in point 6. Kindly correct language.

**Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.



Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 9**

**IEC code:** 2022-68-DT-126

**Type of submission:** Project Drug/device trials

**Title of project:** In vitro susceptibility of Ceftriaxone or Ceftriaxone combination with Sulbactam & Tazobactam in community acquired and nosocomial infections against gram-negative and gram - positive bacteria

**PI:** Dr Ujjala Ghoshal

**Department:** Microbiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr. Manuka Khanna

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Submit ethical clearance from other centers.
2. CTA: mentions sponsor/CRO in the document. Sponsor should therefore be arrayed as a party.
3. CTA, Pg5: Point 5 and 6 are the same.
4. CTA: the budget does not mention the currency (Rs).
5. CTA, Pg 5, point e (iv): Add 'that a notice would be given to the PI'.
6. CTA, Pg 4, point b (iv): correct the language of the statement.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 10**

**IEC code:** 2022-69-DT-126

**Type of submission:** Project Drug/device trials

**Title of project:** A randomized, double blind, parallel group, active controlled, multicentric, phase III study comparing the efficacy, safety and tolerability of Lifitegrast 5% eye drops in patients with dry eye disease.

**PI:** Dr Vikas Kanaujia

**Department:** Ophthalmology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Dr. Manuka Khanna

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The PI is not in the list of DCGI approval and CTRI. Kindly submit document for inclusion of site.
2. Introduction and summary mention about 'Glaucoma'. It should mention about 'dry eyes'.
3. Kindly clarify if the side-effects decrease in vision and altered taste are transient/long-lasting? The PID should clearly state these adverse effects and their frequency.

4. The PID could be much simpler in language.
5. CTA, point 15.1 and 15.2 mentions about PI/CRO. It should be clearly mentioned as either PI or CRO.
6. CTA, Pg 11 point 25-mentions 'courts in Hyderabad'. Kindly change it to 'Courts in Lucknow'.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 11**

**IEC code:** 2022-70-DT-126

**Type of submission:** Project Drug/device trials

**Title of project:** Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Efficacy and Safety of LIB003 in Patients With Cardiovascular Disease on Stable Lipid-Lowering Therapy Requiring Additional Low-Density Lipoprotein Cholesterol Reduction

**PI:** Dr Aditya Kapoor

**Department:** Cardiology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr A K Srivastava

Primary reviewer Legal: Judge (Retd.) Vijai Varma

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. CTA, Pg 383: Sponsor should be made party or write sponsor/CRO.
2. CTA: Include a dispute resolution clause.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee:**

The recommendation of the Member Secretary/3-Member Committee/Expedite Review Committee (EXP meeting no. 46, agenda 12-28) who has given clearance for the proposals has been approved by the committee.

**Agenda No. 12**

**IEC code:** 2022-33-IMP-EXP-46

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Respiratory viral infections in NICU of Northern India: A prospective observational study

**PI:** Dr Akanksha Verma

**Department:** Neonatology

**Subject:** Expedite review project for IEC notification

**Agenda No. 13****IEC code:** 2022-34-EMP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Evaluating the Potential role of cell free DNA (cfDNA) as non-invasive biomarker for prognosis and residual disease monitoring in patients with Diffuse Large B cell Lymphoma.**PI:** Dr Khaliqur Rahman**Department:** Clinical Hematology**Subject:** Expedite review project for IEC notification**Agenda No. 14****IEC code:** 2022-35-EMP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Role of miR-451 in kidney disease associated proteomic deregulation**PI:** Dr Swasti Tiwari**Department:** Molecular Medicine**Subject:** Expedite review project for IEC notification**Agenda No. 15****IEC code:** 2022-36-IP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Serum and Urinary levels of circulating CXCL9, a biomarker targeting IFN- $\gamma$  production in SLE patients**PI:** Dr Amita Aggarwal**Department:** Clinical Immunology**Subject:** Expedite review project for IEC notification**Agenda No. 16****IEC code:** 2022-38-MCh-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Comparative study of dunking and modified dunking versus duct to mucosa techniques of pancreaticojejunostomy**PI:** Dr Rajan Saxena**Department:** Surgical Gastroenterology**Subject:** Expedite review project for IEC notification**Agenda No. 17****IEC code:** 2022-39-SRF-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Study of Human Oncogenic virus and Molecular Pattern correlated with differentiated thyroid cancer**PI:** Dr Gyan Chand**Department:** Endocrinology**Subject:** Expedite review project for IEC notification**Agenda No. 18****IEC code:** 2022-40-EMP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Elucidation of genetic determinants of transmission of carbapenemases in environmental isolates of Gramnegative bacteria.**PI:** Dr Chinmoy Sahu**Department:** Microbiology**Subject:** Expedite review project for IEC notification**Agenda No. 19****IEC code:** 2022-41-EMP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** Cytomegalovirus antiviral resistance in solid organ and hematopoietic stem cell transplant recipients**PI:** Dr Atul Garg**Department:** Microbiology**Subject:** Expedite review project for IEC notification**Agenda No. 20****IEC code:** 2022-42-EMP-EXP-46**Type of submission:** Expedite review project for IEC notification**Title of project:** The role of epitranscriptomic markers of glioma in oncogenesis and clinical outcome

**PI:** Dr AK Jaiswal  
**Subject:** Expedite review project for IEC notification

**Department:** Neurosurgery

**Agenda No. 21**

**IEC code:** 2022-43-MCh-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Portal Biliopathy - analysis of surgical management options : A single center experience

**PI:** Dr Rajan Saxena

**Department:** Surgical Gastroenterology

**Subject:** Expedite review project for IEC notification

**Agenda No. 22**

**IEC code:** 2022-44-SRA-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Early non-invasive approach using placental derived Extracellular vesicle in aneuploidy diagnosis

**PI:** Dr Swasti Tiwari

**Department:** Molecular Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 23**

**IEC code:** 2022-45-EMP-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Deciphering the inter-relationship of Copy Number Variations (CNV) and Mono-/Biallelic TP53 Inactivation in different Genetic Subgroups of Multiple Myeloma

**PI:** Dr Manish Kumar Singh

**Department:** Clinical Hematology

**Subject:** Expedite review project for IEC notification

**Agenda No. 24**

**IEC code:** 2022-48-MCh-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Anticipatory Extended Cholecystectomy

**PI:** Dr Rajan Saxena

**Department:** Surgical Gastroenterology

**Subject:** Expedite review project for IEC notification

**Agenda No. 25**

**IEC code:** 2022-49-IP-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** "Teleconsultation in Post-COVID-19 ICU survivors: An assessment of physical, mental and cognitive status"

**PI:** Dr Shreyas Hanumantrao Gutte

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 26**

**IEC code:** 2022-55-IP-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Diabetic muscle infarction: experience from tertiary care center in India

**PI:** Dr Subhash Yadav

**Department:** Endocrinology

**Subject:** Expedite review project for IEC notification

**Agenda No. 27**

**IEC code:** 2022-59-IMP-EXP-46

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Delineation and the local calibration of computer-aided detection (CAD) software thresholds and associated parameters for detection of pulmonary tuberculosis

**PI:** Dr Alok Nath

**Department:** Pulmonary Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 28**

**IEC code:** 2022-60-EMP-EXP-46

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Role of Toll-like Receptors in Bone Marrow Mesenchymal Stem Cell Dysfunctions in Aplastic Anemia

**PI:** Dr Naresh Kumar Tripathy

**Department:** Clinical Hematology

**Subject:** Expedite review project for IEC notification

**D. Notification for Amendments/Addendum:**

**Agenda No. 29**

**IEC code:** 2019-164-EMP-111

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Study on Polio and Non-Polio enterovirus infections in children with immunodeficiency at multiple medical institutes across India

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Amendment report (2 Year extension for entering Phase II of the study, This will include 13 more centers across India, making it a total of 20 center study. We will continue following the same protocol).

**Committee has noted and approved.**

**Agenda No. 30**

**IEC code:** 2019-178-DT-111

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Protocol I4V-MC-JAHU: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less than 18 Years Old with Systemic Juvenile Idiopathic Arthritis.

**PI:** Dr Amita Aggarwal

**Department:** Clinical Immunology

**Subject:** Amendment report (Amendment D, Approval date: 18th February 2022).

**Committee has noted.**

**Agenda No. 31**

**IEC code:** 2020-331-DT-117

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Amendment report (Notification of update Investigator Undertaking and Notification of revised Case report form Version 5.0).

**Committee has noted.**

**Agenda No. 32**

**IEC code:** 2020-331-DT-117

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Study related documents for review and approval (Protocol No. LUF-44-005 version no. 4.0 dated December 3 2021)

**Committee has noted.**

**Agenda No. 33**

**IEC code:** 2020-78-DM-115

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Endoscopic variceal ligation alone or in combination with non-selective beta blocker for secondary prophylaxis in children with portal hypertension- A Randomised control trial

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Amendment report (Request to extend for 2 years till July 2024).

**Committee has noted and approved.**

**Agenda No. 34**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical Hematology

**Subject:** Amendment report (Change Investigator's Brochure Edition 10.1 dated 18-Jan-2021 to Edition 11 dated 12-May-2021).

**Committee has noted.**

**Agenda No. 35**

**IEC code:** 2021-309-EMP-EXP-44

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Renal transcriptome regulation in kidney disease

**PI:** Dr Swasti Tiwari

**Department:** Molecular Medicine

**Subject:** Amendment report (Amended study Title: **Renal transcriptome regulation in diabetic kidney disease**).

**Committee has noted.**

**Agenda No. 36**

**IEC code:** 2021-311-DM-EXP-44

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Breast artery calcification- A predictor of coronary artery disease in Women? A hospital-based study in Indian women (BAC-CAD Study).

**PI:** Dr Roopali Khanna

**Department:** Cardiology

**Subject:** Amendment report (Additional Investigation, Study duration increases from 1 year to 3 years, Sample size increases from 300 to 600, Amended study proposal summary, Revised Hindi & English PID and Email Printout of ICMR approval).

**Committee has noted and approved.**

**Agenda No. 37**

**IEC code:** 2021-87-MD-EXP-37

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Detection of Beta Thalassemia trait in deferred blood donors for low Hemoglobin using Mathematical formulas obtained by Red cell indices.

**PI:** Dr Rajendra Chaudhary

**Department:** Transfusion Medicine

**Subject:** Amendment Report (Sample size reduced from 1500 to 500).

**Committee has noted and approved.**

**Agenda No. 38**

**IEC code:** 2021-9-MD-118

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A prospective randomized **control** study to compare the efficacy of "Between the fingers Grip" with conventional "Pen holding Grip" to hold an endotracheal tube for orotracheal intubation.

**PI:** Dr Prabhat Tewari

**Department:** Anaesthesiology

**Subject:** Amendment report (Sample size increase from 100 to 300 and study title change : from control word instead Interventional).

**Committee has noted and approved. Submit copy of CTRI.**

**E. Notification for protocol deviation:**

**Agenda No. 39**

**IEC code:** 2020-329-DT-117

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Protocol deviation (Subject no. 41050118).

**Committee has noted.**

**Agenda No. 40**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Protocol deviation (41050118 and 41050100).

**Committee has noted.**

**Agenda No. 41**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** DR Sanjeev

**Department:** Clinical Hematology

**Subject:** Protocol deviation (Subject no. 2100001, 2100002, 2100003 and 2100004)

**Committee has noted.**

**F. General Notification:**

**Agenda No. 42**

**IEC code:** 2018-67-DT-103

**Type of submission:** General Notification

**Title of project:** "A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOWER)"

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC notification of Clinical Study Report version 1.0 dated 11 Jan 2022.

**Committee has noted.**

**Agenda No. 43**

**IEC code:** 2020-201-EMP-115

**Type of submission:** General Notification

**Title of project:** Digoxin in patients with rheumatic heart disease - a randomized placebo-controlled trial

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Notification of Site Activation.

**Committee has noted.**

**Agenda No. 44**

**IEC code:** 2020-201-EMP-115

**Type of submission:** General Notification

**Title of project:** Digoxin in patients with rheumatic heart disease - a randomized placebo-controlled trial

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** Notification of Insurance certificate (Policy no. 272300/48/2022/3622 and period of Insurance: from 21/02/2022 to 20/02/2023)

**Committee has noted.**

**Agenda No. 45**

**IEC code:** 2020-329-DT-117

**Type of submission:** General Notification

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC notification of Blank eCRF version 4.0 dated 12 Oct 2021.

**Committee has noted.**

**Agenda No. 46**

**IEC code:** 2020-329-DT-117

**Type of submission:** General Notification

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Documents for IEC notification (SDMC form dated 06 Oct 2021 and SDMC form dated 16 Feb 2022).

**Committee has noted.**

**Agenda No. 47**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Documents for IEC notification (Case report form version 5.0 dated 16-Feb-2022 and DCGI notification of eCRF version 5.0).

**Committee has noted.**

**Agenda No. 48**

**IEC code:** 2021-180-DT-121

**Type of submission:** General Notification

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Nephrology

**Subject:** Notification of Insurance certificate (Policy no. P0422200001/9999/100188 and period of Insurance: from 01/01/2022 to 31/12/2022).

**Committee has noted.**

**Agenda No. 49**

**IEC code:** 2021-263-EMP-123

**Type of submission:** General Notification

**Title of project:** A multicenter, single-arm, open-label, phase 4 study to evaluate the safety and efficacy of vedolizumab in Indian patients with ulcerative colitis and Crohn's disease

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

**Subject:** IEC notification of remote monitoring plan.

**Committee has noted.**

**G. SAE:**

**Agenda No. 50**

**IEC code:** 2020-286-DT-116

**Type of submission:** SAE reports-Outside-Log



**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Off-site safety report (Subject ID: 1201-002).

**Committee has noted.**

**Agenda No. 51**

**IEC code:** 2020-232-EMP-EXP-27

**Type of submission:** SAE reports-SGPGI

**Title of project:** To evaluate efficacy of Bacillus Calmette-Guerin (BCG) in Reducing the Incidence and severity of COVID-19 in the high-risk population (BRIC): a phase III, Multicentric, Quadruple blind Randomized controlled trial

**PI:** Dr Sushil Gupta

**Department:** Endocrinology

**Subject:** Onsite Adverse Drug Event report (Adverse event term: Cardio Respiratory Failure, Outcome: Fatal, Date of onset 24-April-2021, Case no. ICMR82 and Annual Progress report dated:04-05-2022).

**Committee has noted. The SAE will be discussed by the SAE subcommittee.**

**Agenda No. 52**

**IEC code:** 2020-232-EMP-EXP-27

**Type of submission:** SAE reports-Summary

**Title of project:** To evaluate efficacy of Bacillus Calmette-Guerin (BCG) in Reducing the Incidence and severity of COVID-19 in the high-risk population (BRIC): a phase III, Multicentric, Quadruple blind Randomized controlled trial

**PI:** Dr Sudeep Kumar

**Department:** Cardiology

**Subject:** SUSAR report (Quarterly summary report dated 01-Dec-2021, Period covered from 01-Sep-2021 to 30.Nov-2021)

**Committee has noted.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 53**

**IEC code:** 2017-164-EMP-99(A)

**Type of submission:** Final/Annual/Progress reports

**Title of project:** "The Indian Movement Disorder Registry and Biobank: Clinical and Genetic Evaluation of Movement Disorders in Indian Patients"

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Annual Progress report dated 06.04.2022.

**Committee has noted.**

**Agenda No. 54**

**IEC code:** 2017-12-EMP-95

**Type of submission:** Study Close out Notification

**Title of project:** Plasma exosomal micro RNA and proteome profiling in autism spectrum disorder children: probing for biomarkers

**PI:** Dr Sarita Agarwal

**Department:** Medical Genetics

**Subject:** Study completion report (Date of termination: 5th Sept 2021).

**Committee has noted.**

**Agenda No. 55**

**IEC code:** 2017-149-EMP-99(A)

**Type of submission:** Study Close out Notification

**Title of project:** Genotyping of polymorphic variations at quantitative trait loci on genetic modifier genes and its correlation with fetal hemoglobin levels in homozygous beta thalassemia patients.

**PI:** Dr Sarita Agarwal

**Department:** Medical Genetics

**Subject:** Study completion report (Date of termination: 24-Nov-2021).

**Committee has noted.**

**Agenda No. 56**

**IEC code:** 2018-107-EMP-EXP

**Type of submission:** Study Close out Notification

**Title of project:** Study on Genetic Heterogeneity in Orofacial Clefts: Cleft Lip and Palate in Indians

**PI:** Dr Sarita Agarwal

**Department:** Medical Genetics

**Subject:** Study completion report (Date of termination: 5th Sept 2021).

**Committee has noted.**

**Agenda No. 57**

**IEC code:** 2020-284-DT-116

**Type of submission:** Study Close out Notification

**Title of project:** A 12-week phase 3, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety of once monthly subcutaneous erenumab 70 mg in adult chronic migraine patients

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Notification of Study close out visit dated 14 Feb 2022.

**Committee has noted.**

**Agenda No. 58**

**IEC code:** 2021-105-DM-EXP-38

**Type of submission:** Study Close out Notification

**Title of project:** Esophageal strictures in children: etiology, management and outcome

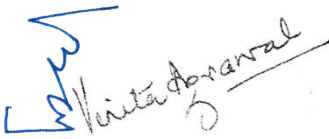
**PI:** Dr Ujjal Poddar

**Department:** Ped. Gastroenterology

**Subject:** Study Completion report (Date of termination: 03-08-2021).

**Committee has noted.**

Dr Col Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow



(Dr. Vinita Agrawal)  
Member Secretary,  
IEC, SGPGI



(Dr. Chandishwar Nath)  
Chairman,  
IEC, SGPGI

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 127<sup>th</sup> Institutional Ethics Committee** meeting held on Saturday, 23<sup>rd</sup> July 2022, at 10.30 am, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

**Present:**

1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
2. Prof. Aneesh Srivastava, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Member
3. Justice S.C Verma, <i>Retd.</i> High Court Judge Allahabad -	Member
4. Shri. Vijai Varma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
5. Shri. Sharat Pradhan, Senior Journalist, (B-4, Dilkusha Colony, Lucknow	Member
6. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
7. Dr. Mohan Gurjar, Additional Professor, Department of CCM, S G P G I M S, Lucknow	Member
8. Prof. M. K. Mitra Former HOD Medicine, KGMU, Lucknow	Member
9. Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow	Member
10. Prof. V.L Bhatia, Prof. Department of Endocrinology, S G P G I M S, Lucknow	Member
11. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
12. Prof. A.K Srivastava, <i>Retd.</i> Prof. Department of Sociology, University of Lucknow	Member
13. Dr. Gautam Palit, Ex-Head, Div. of Pharmacology & Seni. Dep. Dir. & Medical Officer, CSIR-CDRI, Lko.	Member
14. Dr. S. Srivastava, <i>Retd.</i> Scientist-IV, Research Cell, S G P G I M S, Lucknow	Member
15. Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P G I M S, Lucknow	Member Secretary

Members Dr Aneesh Srivastava and Justice SC Verma, could not attend the meeting due to other commitments.

**Determination of quorum:** quorum was complete: 13 members present, with 10 non-institutional members.

**A: General discussions and confirmation of Minutes:**

The Chairman, Dr Chandishwar Nath, welcomed all members. Member Secretary, Dr Vinita Agrawal, proposed to conduct a 'CME on Clinical Trials' on 14<sup>th</sup> October and GCP workshop on 15<sup>th</sup> October 2022, on behalf of the IEC and Bioethics Cell. A tentative program was proposed. All members agreed and the Chairman suggested that the tentative program can be circulated by email for inputs and suggestions.

**Disclosure of conflict of interest:** Chairman, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting.

None of the members declared any conflict of interest.

**Reading and approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 126<sup>th</sup> IEC meeting held on 21<sup>st</sup> May, 2022. All members approved the minutes.

**Agenda No. 1****IEC code:** 2022-76-IMP-127**Type of submission:** Project Intramural**Title of project:** Comparison of Sugammadex and Neostigmine for reversal of Vecuronium induced neuromuscular blockade in paediatric patients: A prospective randomized study**PI:** Dr Aarti Agarwal**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Why the study is essential to conduct in a vulnerable population of children 1-12 yrs. age?
2. Has DCGI approved Sugammadex for pediatric use in India? If yes, submit documentary evidence.
3. Please clarify randomization method in details.
4. English PID:
  - a. What is the purpose of study? It is written "this drug has been sponsored by SGPGI"; the study is sponsored not the drug.
  - b. What are the side effects of taking part? It is stated that "Sugammadex has been shown to be devoid of side effects which neostigmine has, hence it would be safer to use Sugammadex than neostigmine for reversal of muscle paralysis." It should clearly describe the side effects of Sugammadex.
5. Submit Departmental Research Committee document.
6. Submit Child assent form.
7. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision Major Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 2****IEC code:** 2022-81-IMP-127**Type of submission:** Project Intramural**Title of project:** Oral JAK Inhibitor Tofacitinib In Enthesitis Related Arthritis Variant Of Juvenile Idiopathic Arthritis: A Single Center Double Blinded Randomized Control Study**PI:** Dr Naveen R**Department:** Clinical Immunology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Page 12 , 'the two arms include 1. Tofacitinib 5 mg BD/OD (based on body weight) plus Standard of care (Methotrexate plus NSAIDs) 2. Sulfasalazine (up to 2g/day) plus

Standard of care (Methotrexate plus NSAIDs). Oral steroid any dose is continued or tapered down based on the response in both arms. The dose of steroids is suggested to be similar in both arms.

2. Submit PID and consent form for Legally Accepted Representative.
3. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.
4. Give travel costs for participants, if they are being called for visits only for the study.

#### **Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

#### **Agenda No. 3**

**IEC code:** 2022-84-IMP-127

**Type of submission:** Project Intramural

**Title of project:** The role of Plasminogen Activator Inhibitor-1 as a contributor to the pathogenesis of anti-phospholipid syndrome

**PI:** Dr Koshy Nithin Thomas

**Department:** Clinical Immunology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Please confirm if the controls are age-matched. Who will be the pediatric controls?
2. PID "Some of the blood sample will be stored for future studies"; amount of blood collected for which future studies should be written precisely.
3. There should be an option for agreeing to participate in the present study but refusal to give blood for future study.
4. Submit assent form for children aged 7-<18 yrs. Clarify on title of PID that it is for Legally Accepted Representative (LAR).

#### **Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

#### **Agenda No. 4**

**IEC code:** 2022-80-EMP-127

**Type of submission:** Project Extramural

**Title of project:** Prevalence and Risk Factors for Colorectal Polyps/Cancers in Indian Population: A Prospective Multicentre Study

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Submit Ethical clearance from other centers. The ethical clearance from primary center (Apollo, Kolkata) should be submitted.
2. Mention the source of funds.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 5**

**IEC code:** 2022-82-EMP-127

**Type of submission:** Project Extramural

**Title of project:** Functional dyspepsia with and without delayed gastric emptying: symptom severity, quality of life, and fasting and post-water load electrogastronomy parameters

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention the source of funds for the EGG; it has not been mentioned in the budget. The EGG should be free of charge and mention in the PID that there will be no charge for EGG test.
2. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 6**

**IEC code:** 2022-86-DM-127

**Type of submission:** Project DM/MCh/MD

**Title of project:** Use of transcutaneous electric nerve stimulation for treatment of restless leg syndrome in chronic liver disease patients

**PI:** Dr Vimal Kumar Paliwal  
Primary reviewer (Technical): Dr Gautam Palit  
Primary reviewer PID and CF: Dr A K Srivastava  
**Subject:** Project for review

**Department:** Neurology

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Page 15, Period of study should be July/August, not June.
2. PID: It should be included that there will be no extra charges for TENS and iron treatment in patients with low ferritin, if these are not the part of routine treatment.
3. Hindi PID, point 3: has translated 'culture' to 'sanskriti'. Please check and correct. 'Vishay' should be replaced by 'pratibhagi'.
4. Submit RLSS scoring in English also.
5. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 7**

**IEC code:** 2022-75-PDCC-127

**Type of submission:** Project SRF/PDF/PDCC

**Title of project:** Comparison of venous blood gas with arterial blood gas in reducing pain in neonates: An open label randomized controlled trial

**PI:** Dr Akanksha Verma

**Department:** Neonatology

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has asked the PI to consider the following questions and suggestions:

1. Due to the randomization, is it correct to say that some newborns who need PaO<sub>2</sub> and PaCO<sub>2</sub> estimation will have below standard of care if randomized to the venous sampling arm? and some newborns who don't need these estimations, and only need pH and HCO<sub>3</sub>, will have unnecessary undergo arterial sampling?
2. Is arterial sampling already known to have the difficulties mentioned in the secondary aims, such as greater no. of pricks, greater no. of specialized personnel such as doctor instead of nurse, greater time taken for the sampling, and lower comfort level with the procedure?
3. Title should be corrected to comparison of the sampling procedure.

4. The project cannot be approved in the present form. However, if the primary outcome i.e., pain to the neonate, assessed without randomization as an observational study, the project can be resubmitted.

**Decision Major Modification.** Resubmit.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

### **C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee**

The recommendation of the Member Secretary/Expedite Review Committee for the agenda 8 to 13 (clarifications submitted for proposals discussed in 126<sup>th</sup> IEC meeting and for EXP meeting no. 47, agenda 8-9;) who has given clearance for the proposals has been approved by the committee.

#### **Agenda No. 8**

**IEC code:** 2022-64-EMP-EXP-47

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Antinuclear Antibody Immunofluorescence Patterns in Systemic Lupus Erythematosus: Diagnostic and Prognostic Evaluation using Artificial Intelligence

**PI:** Dr Amita Aggarwal  
Immunology

**Department:** Clinical

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 9**

**IEC code:** 2022-65-IP-EXP-47

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Natural history and predictors of response to therapy in children with autoimmune liver disease

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 10**

**IEC code:** 2022-58-EMP-126

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Knowledge, attitude and practice (KAP) survey of low fermentable oligo-, di-, mono-saccharide and polyol (FODMAP) diet awareness among Indian gastroenterologists and physicians

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

**Subject:** Clarification submitted by Dr U C Ghoshal Prasad Dept. of Gastroenterology and approved by Member Secretary for notification

#### **Agenda No. 11**

**IEC code:** 2022-66-IMP-126

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Anti fibrotic effect of tadalafil in liver fibrosis: an in vitro and in vivo study

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

**Subject:** Clarification submitted by Dr Vikas Agarwal Dept. of Clinical Immunology and approved by Member Secretary for notification



**Agenda No. 12**

**IEC code:** 2022-68-DT-126

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** In vitro susceptibility of Ceftriaxone or Ceftriaxone combination with Sulbactam & Tazobactam in community acquired and nosocomial infections against gram-negative and gram -positive bacteria

**PI:** Dr Ujjala Ghoshal

**Department:** Microbiology

**Subject:** Clarification submitted by Dr Ujjala Ghoshal Dept. of Microbiology and approved by Member Secretary for notification

**Agenda No. 13**

**IEC code:** 2022-71-PhD-126

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Complex omics signatures for different stages of ARDS and translation strategies for improved clinical management

**PI:** Dr Afzal Azim

**Department:** Critical Care Medicine

**Subject:** Clarification submitted by Dr Afzal Azim Dept. of Critical Care Medicine and approved by Member Secretary for notification

**D. Notification for Amendments/Addendum:**

**Agenda No. 14**

**IEC code:** 2019-30-IP-108

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A randomized study of Consolidation Chemoradiation versus Observation after first line Chemotherapy in Locally Advanced Carcinoma Gallbladder

**PI:** Dr Sushma Aggarwal

**Department:** Radiotherapy

**Subject:** Amendment report (Extend for 1 year and Omental metastases as evident on CT scan without ascites, Limited liver metastases (<5) in same segment as liver infiltration).

**Committee has noted and approved.**

**Agenda No. 15**

**IEC code:** 2020-179-MCh-EXP-

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Clinico-pathological profile and surgical outcome of non-functioning Adrenal tumours- 30 years experience

**PI:** Dr Gyan Chand

**Department:** Endocrine Surgery

**Subject:** Amendment Report (Amend study period: 21 years and Change study title: Clinico-pathological profile and surgical outcome of non-functioning Adrenal tumours- 21 years experience).

**Committee has noted and approved.**

**Agenda No. 16**

**IEC code:** 2020-320-PhD-117

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Effect of Circulating Microparticles on Monocyte Activation and Differentiation in IgA Nephropathy

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Amendment report ( Numer of patients enrolled from 40 to 70).

**Committee has noted and approved.**

**Agenda No. 17**

**IEC code:** 2020-331-DT-117

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** Amendment report (Request for 1 month extension of IEC approval).

**Committee has noted and approved.**

**Agenda No. 18**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** DR Sanjeev

**Department:** Clinical

Hematology

**Subject:** Amendment report (Change Investigator's Brochure from Edition 11 to Edition 12 dated 12 May 2022).

**Committee has noted and approved.**

**Agenda No. 19**

**IEC code:** 2022-20-IMP-125

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Role of betablocker and norepinephrine in the outcome of stroke.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Amendment report (From Previous Sample Size 49 in each arm to new sample size 56 in each group).

**Committee has noted and approved.**

**E. Notification for protocol deviation:**

**Agenda No. 20**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Notification for protocol deviation (Subject No. 41050118 and 41050100).

**Committee has noted.**

**Agenda No. 21**

**IEC code:** 2021-177-DT-121

**Type of submission:** Notification for protocol deviation

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev Jha

**Department:** Clinical Hematology

**Subject:** Notification for protocol deviation (Patient No. and name: 2100002 and DK).

**Committee has noted.**

**E. General Notification:**

**Agenda No. 22**

**IEC code:** 2017-160-DT-99(A)

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization A Phase IV study

**PI:** Dr Raghunandan Prasad

**Department:** Radiodiagnosis

**Subject:** Clinical Study Report (CSR) for IEC notification and site filing.

**Committee has noted.**

**Agenda No. 23**

**IEC code:** 2019-193-DT-112

**Type of submission:** General Notification

**Title of project:** Flow Effect of semaglutide versus placebo on the progression of renal impairment in subject with type 2 diabetes and chronic kidney disease

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Clinical trials Insurance policy (Policy No.: 030P000302901000 and Period of Insurance: 01-09-2021 to 31-08-2022) Certificate of Insurance Clinical Tests and Trials (Policy No.:390-08654942-30078 and Period of Insurance: 1 year & Expiry Date: April 30, 20

**Committee has noted.**

**Agenda No. 24**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Lab Manual version 3.1.0 (Manual created: 23 March 2020 and Manual Revised: 28 September 2021).

**Committee has noted.**

**Agenda No. 25**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Lab Manual version 4.1.0 (Manual Created 23 March 2020 and Manual Revised 11 January 2022).

**Committee has noted.**

**Agenda No. 26**

**IEC code:** 2020-329-DT-117

**Type of submission:** General Notification

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** IEC notification of Insurance (Policy number: 4067/204322356/00/000 and Policy period from: August 19th, 2020 to April 30th, 2025).

**Committee has noted.**

**Agenda No. 27**

**IEC code:** 2021-177-DT-121

**Type of submission:** General Notification

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Error in ECG report (Subject No.: 2100007 and 2100008).

**Committee has noted.**

### **G. SAE:**

#### **Agenda No. 28**

**IEC code:** 2020-286-DT-116

**Type of submission:** SAE reports-Outside-Log

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from dated 29- Oct -2021 to 26 Jan 2022.

**Committee has noted.**

#### **Agenda No. 29**

**IEC code:** 2020-286-DT-116

**Type of submission:** SAE reports-Outside-Log

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from dated 27- Oct -2021 Subject no.: 1103-003.

**Committee has noted.**

#### **Agenda No. 30**

**IEC code:** 2020-286-DT-116

**Type of submission:** SAE reports-Outside-Log

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Notification of CIOMS from dated 27- Jan-2021 to 30-Apr-2022.

**Committee has noted.**

#### **Agenda No. 31**

**IEC code:** 2021-177-DT-121

**Type of submission:** SAE reports-Outside-Log

**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.

**PI:** Dr Sanjeev

**Department:** Clinical

Hematology

**Subject:** Suspected Unexpected Serious Adverse Reaction (Period: 01 October 2021 to 31 March 2022).

**Committee has noted. Clarify if there is any SAE in this center, SGPGI.**

Dr Col Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 32**

**IEC code:** 2021-179-DT-121

**Type of submission:** SAE reports-Outside-Log

**Title of project:** A multicenter, single-arm, open label trial to evaluate efficacy and safety of oral, twice daily LNP023 in adult aHUS patients who are naïve to complement inhibitor therapy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Suspected Unexpected Serious Adverse Reaction (Period: 01 October 2021 to 31 March 2022, Total Number of Cases: 2, Pat. No: 1002006 and 5501002).

**Committee has noted. Clarify if there is any SAE in this center, SGPGL.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 33**

**IEC code:** 2018-127-EMP-105

**Type of submission:** Final/Annual/Progress reports

**Title of project:** Multi Centric Collaborative Study of National Registry for Rare Disorders in India

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Annual Progress report dated 07-06-2022.

**Committee has noted.**

**Agenda No. 34**

**IEC code:** 2014-161-EMP-EXP

**Type of submission:** Study Close out Notification

**Title of project:** Alterations in cell signaling pathways in bladder cancer progression a tissue microarray expression analysis of primary and recurrent tumors

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Study completion report (Date of termination: June 2020).

**Committee has noted.**

**Agenda No. 35**

**IEC code:** 2015-109-IMP-EXP

**Type of submission:** Study Close out Notification

**Title of project:** Role of peritubular capillary morphometry in the diagnostic evaluation of renal allograft biopsies

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Study Completion report dated 01.07.2022.

**Committee has noted.**

**Agenda No. 36**

**IEC code:** 2017-129-PhD-99

**Type of submission:** Study Close out Notification

**Title of project:** Endothelial injury and circulating Microparticles in IgA Nephropathy

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Study Completion report (Date of termination: 24 June 2022).

**Committee has noted.**

**Agenda No. 37**

**IEC code:** 2017-178-IMP-99(B)

**Type of submission:** Study Close out Notification

**Title of project:** Analysis of sequence variations in MEOX1, GDF3 and GDF6 genes in cases with congenital craniovertebral junction anomalies

**PI:** Dr Jayesh Sardhara

**Department:** Neurosurgery

**Subject:** Study Close out Notification (Date of termination: 05/05/2022).  
**Committee has noted.**

**Agenda No. 38**

**IEC code:** 2017-232-MD-EXP

**Type of submission:** Study Close out Notification

**Title of project:** "A Clinicopathological Study of Renal Amyloidosis"

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Study completion report (Date of termination: 31st Oct. 2019).

**Committee has noted.**

**Agenda No. 39**

**IEC code:** 2018-58-SRF-EXP

**Type of submission:** Study Close out Notification

**Title of project:** MiRNA-21 in the fibrogenic pathway in IgAN

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Study Completion report (Date of termination: 24 June 2022).

**Committee has noted.**

**Agenda No. 40**

**IEC code:** 2021-159-CP-EXP-40

**Type of submission:** Study Close out Notification

**Title of project:** Validation of the IMPACT-III instrument to assess the quality of life of Indian children with Inflammatory Bowel disease: A multicentre study

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Study close out report (Date of termination: 20th April 2022).

**Committee has noted.**

**Agenda No. 41**

**IEC code:** 2021-315-SRF-EXP-

44

**Type of submission:** Study Close out Notification

**Title of project:** Circulating Microparticles and Monocyte Activation in Renal Antibody Mediated Allograft Rejection

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Premature termination report dated 08-July-2022.

**Committee has noted.**

**Agenda No. 42**

**IEC code:** 2021-338-SRF-EXP-

44

**Type of submission:** Study Close out Notification

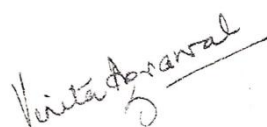
**Title of project:** Stimulatory effects of circulating microvesicles on Monocytic cell lineage in IgAN

**PI:** Dr Vinita Agrawal

**Department:** Pathology

**Subject:** Premature termination report dated 08-July-2022.

**Committee has noted.**



(Dr. Vinita Agrawal)  
Member Secretary,  
IEC, SGPGI



(Dr. Chandishwar Nath)  
Chairman,  
IEC, SGPGI

## SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 128<sup>th</sup> Institutional Ethics Committee** meeting held on Saturday, 24th September 2022, at 10.30 am, through Telemedicine facility, SGPGI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

### Members:

1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
2. Prof. SP Ambesh, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Member
3. Justice S.C Verma, <i>Retd.</i> High Court Judge Allahabad -	Member
4. Shri. Vijai Varma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
5. Shri. Sharat Pradhan, Senior Journalist, (B-4, Dilkusha Colony, Lucknow	Member
6. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
7. Dr. Mohan Gurjar, Additional Professor, Department of CCM, S G P G I M S, Lucknow	Member
8. Prof. M. K. Mitra Former HOD Medicine, KGMU, Lucknow	Member
9. Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow	Member
10. Prof. V.L Bhatia, Prof. Department of Endocrinology, S G P G I M S, Lucknow	Member
11. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
12. Prof. A.K Srivastava, <i>Retd.</i> Prof. Department of Sociology, University of Lucknow	Member
13. Dr. Gautam Palit, Ex-Head, Div. of Pharmacology & Seni. Dep. Dir. & Medical Officer, CSIR-CDRI, Lko.	Member
14. Dr. S. Srivastava, <i>Retd.</i> Scientist-IV, Research Cell, S G P G I M S, Lucknow	Member
15. Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P G I M S, Lucknow	Member Secretary

Dean Dr SP Ambesh and Justice S C Verma, could not attend the meeting, due to prior commitment.

**Determination of quorum:** quorum was complete: 13 members present, with ten non-institutional members.

### A: General discussions and confirmation of Minutes:

The chairman, Dr Chandishwar Nath, welcomed all members. Member Secretary, Dr Vinita Agrawal, informed that Prof SP Ambesh, Head Department of Anesthesiology, SGPGIMS has taken charge as Dean of the Institute and is a member of the IEC. She also informed that a 'CME on Clinical Trials and GCP' will be conducted on Friday, 14<sup>th</sup> October at SGPGIMS from 10am to 5pm. The speakers have given their consent; however, the clarification of online/offline participation has to be sought. The final program will be communicated to all members. All members agreed to participate in the CME.

Dr MK Mitra emphasized that faculty of the Institute should be aware of the CONSORT guidelines for randomized clinical trials to maintain standard of research which can be later published.

The Chairman, Member Secretary and all members were aware that this was the last full board meeting of this Committee. All thanked each other and opined that this has been a learning experience. The committee had many accomplishments in their tenure and had been committed to maintain the highest standards in ethics with dedicated efforts of all. The Chairman on behalf

of the whole committee appreciated Member Secretary, Dr Vinita Agrawal and Bioethics Cell team for their exemplary efforts to arrange meetings, even in COVID times.

**Disclosure of conflict of interest:** Chairman, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting.

The following member did not participate in the deliberations of the following agenda and was out of the committee room during the discussions:

- Dr Vinita Agrawal, PI for the agenda no. 13 (IEC code: 2022-95-EMP-128)

**Reading and approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 127<sup>th</sup> IEC meeting held on 23<sup>rd</sup> July, 2022. All members approved the minutes.

### **B. Review of New Proposals:**

#### **Agenda No. 1**

**IEC code:** 2022-104-IMP-128

**Type of submission:** Project Intramural

**Title of project:** Comparison of pre-oxygenation with a high flow nasal cannula versus simple anatomical mask before intubation during induction of general anesthesia in patients undergoing surgery for cervical spine injury

**PI:** Dr Prateek Singh Basis

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Suggestion to mention 'Randomized control trial' in the Title.
2. Clarify in Method section of the study protocol about (a) Primary outcome, (b) Till what time study observations will be followed?
3. Mention in simple language in the Participant Information Document (PID), about random selection and procedures to be performed.
4. Hindi PID: the translation of subject to 'विषय' is not correct, it should be 'प्रतिभागी'.
5. Submit PID and consent form for Legally Accepted Representative.
6. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

#### **Agenda No. 2**

**IEC code:** 2022-105-IMP-128

**Type of submission:** Project Intramural

**Title of project:** Comparison of Manual Intermittent bolus versus Continuous infusion of 0.2% Ropivacaine after ultrasound guided serratus anterior plane block for rib fractures



**PI:** Dr Prateek Singh Basis  
Primary reviewer (Technical): Dr Mohan Gurjar  
**Subject:** Project for review

**Department:** Anaesthesiology

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Suggestion to mention 'Randomized control trial' in the Title.
2. Mention in simple language in the Participant Information Document (PID), about random selection and procedures to be performed.
3. Hindi PID: the translation of subject to 'विषय' is not correct, it should be 'प्रतिभागी'.
4. Submit PID and consent form for Legally Accepted Representative.
5. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 3**

**IEC code:** 2022-107-IMP-128

**Type of submission:** Project Intramural

**Title of project:** A randomized controlled Study for Clinical evaluation of synergistic effect of oral bisphosphonate with Platelets rich plasma in knee Osteoarthritis

**PI:** Dr Amit Kumar

**Department:** Apex Trauma Centre

Primary reviewer (Technical): Prof. V.L Bhatia

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Kindly clarify if calcium and Vit D3 are prescribed in similar doses to all the patients of osteoarthritis, irrespective of whether they are part of study or not?
2. Simplify the language of Participant Information Document (PID). Do not mention the detailed procedure of preparation and administration of PRP.
3. Mention in PID, about the charges and free component in the study. Since Alendronate is add on to PRP therapy in this study, the cost of Alendronate should be borne by the study.
4. Consent forms should be as per SPO's of IEC. Contact Bioethics Cell for inputs/clarification.
5. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 4**

**IEC code:** 2022-108-IMP-128

**Type of submission:** Project Intramural

**Title of project:** Effect of Three Months Daily Teriparatide Injection in Osteoporotic Intertrochanteric fractures: A Randomised Controlled Trial

**PI:** Dr Kumar Keshav

**Department:** Apex Trauma Centre

Primary reviewer (Technical): Prof. V.L Bhatia

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Participant Information Document (PID) mentions:

- " If you are a part of the group receiving injection, you will have to take daily 20 µgm subcutaneous injection for 3 months, the cost of which would be around Rs.12,000/-".

Teriparatide is add on therapy (Gp 2) in the study. It should be provided free of cost to patients.

- P17 last paragraph: "You will receive several benefits by agreeing to participate in this study. Firstly, you will be followed up more closely than other patients and at more regular intervals. (This means that other patients will not be cared for properly)
- Secondly, you will have our contact number and can revert back to us anytime if you feel the need to. Thirdly, cost of an investigation used to assess osteoporosis amounting to Rs 4000/- would be waived off. And lastly, you may feel proud to be a part of the study which may eventually, in future help many more people like you." (It's a luring and improper.)

This language is improper. Modify and simplify the language of Participant Information Document (PID) and submit a comprehensive PID. Contact Bioethics Cell for inputs/clarification.

2. The cost of PTH injection should be borne by Investigators.

3. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 5**

**IEC code:** 2022-109-IMP-128

**Type of submission:** Project Intramural

**Title of project:** Early versus delayed removal of small calibre percutaneous intercostal drainage catheter and its correlation with infection in cases of acute haemothorax in level 1 trauma centre : A pilot Study

**PI:** Dr Amit Kumar Singh

**Department:** Apex Trauma Centre

Primary reviewer (Technical): Dr Mohan Gurjar

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

1. Suggestion to mention 'Randomized control trial' in the Title.
2. The time of drain removal in hemothorax is according to clinical indication. Will you do repeat CT before drain removal? In some patients, repeat inserion may be required. How will this issue be handled?
3. How will you address, if patients get discharged before 10 days (study period)?
4. How will you address patients with deranged renal function, as study will require contrast media for doing CT scan and this contrast is nephrotoxic?
5. Hindi Participant Information Document (PID): the translation of subject to 'विषय' is not correct, it should be 'प्रतिभागी'. Pg. 18, point 3: drainage as been mentioned as 'जल निकासी'. Kindly mention in scientific language and do not transplate if the meaning is improper.
6. Mention in simple language in the PID, about random selection and procedures to be performed.
7. Submit PID and consent form for Legally Accepted Representative.
8. Submit case record form.
9. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 6**

**IEC code:** 2022-111-IMP-128

**Type of submission:** Project Intramural

**Title of project:** Comparison of the use of LMA Gastro Airway versus sedation and oxygen supplementation with nasal cannula in patients undergoing Endoscopic Retrograde Cholangiopancreatography: A Prospective Randomised Control Study

**PI:** Dr Suruchi

**Department:** Anaesthesiology

**Primary reviewer (Technical):** Dr Mohan Gurjar

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The Participant Information Document (PID) should mention the title of the project and also for whom it has been devised.
2. Only one PID is sufficient as the two groups will be formed after randomization. Submit proper PID. Mention in simple language in the PID, about random selection and procedures to be performed.
3. Hindi Participant Information Document (PID), para 4: it is written 'अच्छे रोगी की वसूली'. Kindly check and reframe senetence with proper wordings. Kindly mention in scientific language and do not transplate if the meaning is improper.
4. In, consent forms, mention 'sample collection' as 'not applicable'.
5. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 7**

**IEC code:** 2022-90-IMP-128

**Type of submission:** Project Intramural

**Title of project:** To Study the Serum Metabolomic markers as predictor of Gestational Diabetes Mellitus in first trimester of pregnancy in North Indian Population: a pilot Study.

**PI:** Dr Indu Lata

**Department:** Maternal & Reprod. Health

Primary reviewer (Technical): Prof. Amita Panday

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The protocol mentions that samples will be collected at first antenatal care visit and stored. Kindly ensure that all the pregnant women are screened and tested for gestational DM at the first antenatal visit.
2. For a group of 40 women with GDM, PI would need to screen a large number of women. Kindly mention in the protocol.
3. The language of the Participant Information Document (PID) is very technical. Kindly simplify and resubmit proper PID.
4. Kindly ensure that participant does not pay for the tests done for the study.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 8**

**IEC code:** 2022-106-EMP-128

**Type of submission:** Project Extramural

**Title of project:** A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashan in Moderately Malnourished Children

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

Primary reviewer (Technical): Prof. V.L Bhatia

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. What is the essentiality to do this study in malnourished children; a highly vulnerable population?
2. Submit copy of the ethical clearance for pilot studies (Preliminary work done earlier) as mentioned on pg. 88.
3. Has Swarnprashan been used in adults? Published literature should be provided.
4. Submit published literature on efficacy and safety of Swarnprashan in pediatric population.

5. The primary outcome is vague. How will the PI monitor the number of visits and frequency of infections which may be dependent on many other factors?
6. The GE toxicity is mentioned once. But there is no clarification about this in the PID or in the protocol regarding type, frequency, management etc.
7. Mention the rationale for sample size.
8. Who will prepare Swarnprashan tablets and do quality control? Ideally in clinical trials preparation should be done by a GMP (Good Manufacturing Practice) certified manufacturing establishment.
9. Diet will be provided by school/aganwadi worker. Will this diet improve malnutrition?
10. Ayurvedic expert should be consulted.
11. Kindly clarify the role of collaborator from the Department of Radiotherapy, KGMU, Lucknow.
12. The committee suggests that this study should be performed in AYUSH Institutes with Ayurvedic physicians as principal investigators. The blood samples can be analyzed by the investigator at SGPGIMS for immune profiling.

**Decision Major Modification.**

PI advised to submit above responses, for consideration in the next IEC meeting.

**Agenda No. 9**

**IEC code:** 2022-113-EMP-128

**Type of submission:** Project Extramural

**Title of project:** Efficacy and safety of levodopa in dystonia due to neurological Wilson disease, an open label placebo controlled randomized clinical trial.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

Primary reviewer (Technical): Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The certificates have not been signed. In future, do not submit improper, unsigned certificates to the Bioethics Cell. Submit duly signed certificates.
2. Kindly mention the source of funding.
3. Clarify and mention about the administration of chelating agent as a standard of care in patients of Wilson disease.
4. As children are being recruited in the study, submit child assent form.
5. Pg. 6, protocol mentions that 'if dystonia increases, the patients will be removed from the study'. They cannot be removed from the study analysis and should be considered as treatment failure. Mention how these patients will be managed.
6. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.
7. Submit a copy of approval letter from the funding agency to the IEC.

**Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 10**

**IEC code:** 2022-89-EMP-128

**Type of submission:** Project Extramural

**Title of project:** Metabolomics and genetic association analysis in ccRCC patients in north Indian population

**PI:** Dr Naveen Kumar Gautam

**Department:** Urology

Primary reviewer (Technical): Dr Vinita Agrawal

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Mention the rationale of 123 healthy controls. Clarify their source and inclusion/exclusion criteria. Kindly correct the term 'healthy patients' to 'healthy controls'
2. Clarify the type of controls in the study and their numbers.
3. Participant Information Document (PID): mention clearly about sample collection.
4. Submit informed consent documents for healthy controls.
5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 11**

**IEC code:** 2022-93-EMP-128

**Type of submission:** Project Extramural

**Title of project:** Investigation of mitochondrial damage associated molecular patterns as potential biomarkers for pregnancy complications

**PI:** Dr J. K Sharma

**Department:** Molecular Medicine

Primary reviewer (Technical): Prof. Amita Panday

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Suggestion to include in the title the specific complications which are being studied 'pre-eclampsia' and 'IUGR'.
2. Mention the source of funding and the distribution among investigators of SGPGI and collaborator.
3. The protocol mentions about pre-existing/stored as well as prospective blood samples. Clarify.
4. Pg 21, clarify control groups (internal and external)
5. Participant Information Document (PID) for controls mentions: "Since you are visiting SGPGIMS for your routine checkups, we would like to request you to participate in the above study as a non-pregnant control." What is the indication of routine check up of young females? Please clarify and mention the source of controls.
6. Submit ethics committee clearance from AIIMS, Patna.
7. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 12**

**IEC code:** 2022-94-EMP-128

**Type of submission:** Project Extramural

**Title of project:** Genotype-phenotype correlation with the efficacy of chelation therapy in pediatric hepatic Wilson disease in North India

**PI:** Dr Moinak Sen Sarma

**Department:** Ped. Gastroenterology

Primary reviewer (Technical): Prof. V.L Bhatia

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Simplify the language of the Participant Information Document (PID) and submit a comprehensive PID.
2. Submit PID for LAR (Legally Accepted Representative).
3. Submit child assent form.
4. Clarify the source of funding. (Page1 mentions: project funded Yes, DHR; Pg 18 of PID mentions: Who is organizing and funding the research/trial? Ans. Principal investigator from Dept of Pediatric Gastroenterology, SGPGIMS is organising. Funding will be sought from the Institute for the research trial).
5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Agenda No. 13**

**IEC code:** 2022-95-EMP-128

**Type of submission:** Project Extramural

**Title of project:** To evaluate the association of donor specific antibodies and protocol biopsy on graft outcome in renal transplant recipients

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Prof. M. K Mitra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify the source of funding (Intramural or DHR).
2. Participant Information Document (PID): explanation to q.6 should be more reassuring.
3. Mention the intervention in the PID.
4. Clarify the total amount of blood to be collected.

5. Submit a copy of approval letter from the funding agency to the IEC.

**Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 14**

**IEC code:** 2022-97-EMP-128

**Type of submission:** Project Extramural

**Title of project:** Repurposing of alpha lipoic acid in breast cancer: Effect on autophagy and energy metabolism of BCSCs

**PI:** Dr Rohit Anthony Sinha

**Department:** Endocrinology

Primary reviewer (Technical): Dr Gautam Palit

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The protocol should include review of literature and associated references. Please submit proper protocol.
2. Get clearance from Stem Cell Research Committee, before the start of study and submit a copy to Bioethics Cells.
3. Submit a copy of approval letter from the funding agency to the IEC.

**Decision Minor Modification.**

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 15**

**IEC code:** 2022-99-EMP-128

**Type of submission:** Project Extramural

**Title of project:** EFFECT OF ORAL SODIUM BICARBONATE ON FGF-23/KLOTHO AXIS AND BONE HEALTH IN PATIENTS WITH CHRONIC KIDNEY DISEASE.

**PI:** Dr Manas Ranjan Behera

**Department:** Nephrology

Primary reviewer (Technical): Prof. M. K Mitra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Kindly provide clarification for the ethical issue related to non-administration of sodium bicarbonate in a group of patients of Grade 2-4 renal failure who require it to combat acidosis.
2. Hindi Participant Information Document (PID): the translation of subject to 'विषय' is not correct, it should be 'प्रतिभागी'.
3. Clarify the source of funding: Indian Society of Nephrology or SGPGIMS.
4. Submit a copy of approval letter from the funding agency to the IEC.



**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 16**

**IEC code:** 2022-110-DM-128

**Type of submission:** Project DM/MCh/MD

**Title of project:** Prospective Randomized Controlled Study Comparing the Diagnostic Yield of Cryo-Endobronchial Biopsy vs Forceps Endobronchial Biopsy in Patients Undergoing Endobronchial Ultrasound Guided Transbronchial Needle Aspiration for Suspected Sarcoidosis

**PI:** Dr Ajmal Khan

**Department:** Pulmonary Medicine

Primary reviewer (Technical/PID & CF: Dr Surendra Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Submit comprehensive Participant Information Document (PID) with explanation of the procedures being performed.
2. Clarify the frequency of performing the procedure.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 17**

**IEC code:** 2022-114-DM-128

**Type of submission:** Project DM/MCh/MD

**Title of project:** Safety and efficacy of vigabatrin add on compared to placebo in Lennox-Gastaut Syndrome: A randomized controlled trial

**PI:** Dr Jayantee Kalita

**Department:** Neurology

Primary reviewer (Technical): Prof. M. K Mitra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The placebo has 'saccharine'. What is the justification for not administering even the alternate standard therapy in patients who are not responding to standard treatment?
2. Mention the source of funding.
3. Participant Information Document (PID) for LAR should mention 'Your child' instead of 'you'.
4. PID mentions: "For participation you will have to give a consent for the treatment and collection of 3ml blood which will used future analysis for understanding disease pathophysiology." Collection of 3ml blood should be optional not compulsion. A patient may give consent to treatment but has right to deny blood sample. Change the statement as "For participation you may give consent for the treatment and if you are willing also for collection of 3ml blood which

will be used for future analysis for understanding disease pathophysiology.”

5. The language of PID should be simplified and mention in PID about side effects and random selection.
6. Clarify the mechanism for management of complications.
7. Get CTRI before start of the study. Submit a copy to Bioethics Cell before start of the study.
8. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**Agenda No. 18**

**IEC code:** 2022-112-CP-128

**Type of submission:** Project Collaborative

**Title of project:** EUS-guided trans-papillary or trans-luminal biliary stenting for malignant biliary obstruction: A prospective randomised comparison

**PI:** Dr Praveer Rai

**Department:** Gastroenterology

Primary reviewer (Technical): Dr Vinita Agrawal

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify the role of collaborator Dr Vinay Dhir.
2. Pg 11 mentions Dr Rahul Shah as PI. His name is not mentioned as collaborator. Please clarify his role and submit ethics committee clearance for S L Raheja hospital, Mumbai.
3. Clarify the source of funding.
4. Participant Information Document (PID) should be comprehensive mentioning the role of SGPGI and collaborating Institution. Pg17, does not mention the name of SGPGIMS.
5. Page 14, PID mentions “Principal investigator will obtain two sets of consent documents from the patient after explaining about this study sufficiently. One is for the patient and the other will be stored in the Department of Gastroenterology, S.L. Raheja Hospital, Mahim, Mumbai. Data centre: Department of Gastroenterology, S.L. Raheja Hospital, Mahim, Mumbai Rhaeja. What is the explanation for this statement?”
6. Mention the cost differences between the procedures being performed in the two groups to assess the fair random selection.
7. CTRI should mention the name of PI from SGPGIMS. Submit a copy to Bioethics Cell before start of the study.
8. Submit a copy of approval letter from the funding agency to the IEC.

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 19**

**IEC code:** 2022-72-DT-128

**Type of submission:** Project Drug/device trials

**Title of project:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Prof. M. K Mitra

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. One of the groups (n=225) will receive a placebo. The contents of the 'placebo' are not clear. Why are a group of patients of IgAN being deprived of the standard therapy? Kindly give a rationale and explanation for this ethical issue.
2. Submit a copy of valid Insurance policy.
3. Submit Ethical Clearance of other sites in India.
4. Mention in Participant Information Document (PID) about the side-effects associated with the drug.
5. Pg 12 PID, clarify 'rule 39'.
6. Submit a copy of CTA.
7. Clarify if blood samples will be collected from patients at SGPGIMS and sent abroad. If yes, submit the required clearance.
8. Clarify if SGPGI will be involved in collection of blood samples for pharmacodynamics or pharmacokinetic studies. If yes, who will do these pharmacodynamics or pharmacokinetic studies?

**Decision** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee:**

The recommendation of the Member Secretary/Expedite Review Committee for the agenda 20 to 23 (EXP meeting no. 48) who has given clearance for the proposals has been approved by the committee.

**Agenda No. 20**

**IEC code:** 2022-101-IMP-EXP-48

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Expression of programmed death-ligand 1 (PD-L1) in pituitary tumors

**PI:** Dr AK Jaiswal

**Department:** Neurosurgery

**Subject:** Expedite review project for IEC notification

**Agenda No. 21**

**IEC code:** 2022-83-DM-EXP-48

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Serum p-glycoprotein as a biomarker of disease activity in Takayasu Arteritis  
**PI:** Dr Durga Prasanna Misra **Department:** Clinical Immunology  
**Subject:** Expedite review project for IEC notification

**Agenda No. 22** **IEC code:** 2022-88-IP-EXP-48  
**Type of submission:** Expedite review project for IEC notification  
**Title of project:** Comparison of Intubation success with conventional laryngoscope and Smart-trach video Laryngoscope by novices: A Randomized Cross-Over Manikin study  
**PI:** Dr Suruchi **Department:** Anaesthesiology  
**Subject:** Expedite review project for IEC notification

**D. Notification for Amendments/Addendum:**

**Agenda No. 23** **IEC code:** 2019-110-DM-109  
**Type of submission:** Notification of Amendments/Addendum  
**Title of project:** Comparison of efficacy and safety of Low (20 mg) vs High (40mg) dose oral Prednisolone in Complex Regional Pain Syndrome  
**PI:** Dr Jayantee Kalita **Department:** Neurology  
**Subject:** Amendment report (Request change Study title, Diabetic Patients with CRPS and).

The committee has given the following suggestions:

- Kindly submit detailed clarification for the need of change in study title.
- Why are Diabetic patients being given prednisolone? Submit in detail the changes from the previous protocol in tabulated manner.
- Clarify the number of participants recruited in the study till date with the earlier protocol.
- The study was approved in 2019, as a DM study; the student would have completed the course by now. How can the changes be incorporated after completion of the study?

**Agenda No. 24** **IEC code:** 2020-171-IP-EXP-24  
**Type of submission:** Notification of Amendments/Addendum  
**Title of project:** Assessment of pain intensity and the association of patient satisfaction with analgesic therapy in patients undergoing spinal instrumentation surgery  
**PI:** Dr Rudrashish Haldar **Department:** Anaesthesiology  
**Subject:** Amendment Report (Request to extend till 20.09.2024 due to COVID pandemic).  
**Committee has noted and approved.**

**Agenda No. 25** **IEC code:** 2020-86-DM-EXP-16  
**Type of submission:** Notification of Amendments/Addendum  
**Title of project:** Pneumococcal vaccination in SLE: Review of evidence, estimation of immunogenicity and cost-effectiveness analysis  
**PI:** Dr Amita Aggarwal **Department:** Clinical Immunology  
**Subject:** Amendment report (Request for 1.5 year extension to complete the new arm study).  
**Committee has noted and approved.**

**Agenda No. 26** **IEC code:** 2021-177-DT-121  
**Type of submission:** Notification for protocol deviation  
**Title of project:** An Indian Multi-centric Iv study to assess the safety of Crizalizinab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises.  
**PI:** Dr Sanjeev **Department:** Clinical Hematology

**Subject:** Protocol deviation (Patient No. and Name initial: 2100003 and SB)

**Committee has noted.**

**Agenda No. 27**

**IEC code:** 2021-180-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A 2-year randomized, 3-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and siponimod versus fingolimod in pediatric patients with multiple sclerosis followed by an open-label extension.

**PI:** Dr Jayantee Kalita

**Department:** Neurology

**Subject:** Amendment report (ICF Core study version 4.0, version date :08-Jun-2022 in English, ICF Core study version 4.0, version date :08-Jun-2022, translated from English to Hindi on 16-Jun-2022, ICF Core study version 4.0, version date :08-Jun-2022 and study related documents).

**Committee has noted.**

**Agenda No. 28**

**IEC code:** 2021-183-IP-EXP-41

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Digital rheumatology for training, practice and research survey exploring practice, perceptions and future alternatives

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

**Subject:** Amendment report (Project was transferred to PI in march 2022 need one year extension).

**Committee has noted and approved.**

**Agenda No. 29**

**IEC code:** 2021-200-IP-EXP-41

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Gender Equity in Rheumatology

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

**Subject:** Amendment report (Project was transferred to PI in march 2022 need one year extension).

**Committee has noted and approved.**

**Agenda No. 30**

**IEC code:** 2021-252-DM-123

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Wrist vs ear pulse oximetry for neonates during resuscitation: a randomised controlled trial

**PI:** Dr Kirti M. Naranje

**Department:** Radiotherapy

**Subject:** Amendment report (Inclusion criteria amend)

**Committee has noted and approved.**

**Agenda No. 31**

**IEC code:** 2021-271-EMP-123

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide as a radiation sensitiser in patients with locally advanced/recurrent breast cancer.

**PI:** Dr Punita Lal

**Department:** Radiotherapy

**Subject:** Amendment report (Summary of changes and Protocol Version 3.0 dated 01.11.2021).

**Committee has noted.**

#### **E. Notification for protocol deviation:**

**Agenda No. 32**

**IEC code:** 2020-329-DT-117

**Type of submission:** Notification for protocol deviation

**Title of project:** A randomized, double blind, multicenter, placebo-controlled phase 3 study with open label period to evaluate the efficacy and safety of Inebilizumab in adults with myasthenia gravis

PI: Dr Jayantee Kalita

Department: Neurology

Subject: Protocol deviation (Subject no. 41050100 and 41050118)

Committee has noted.

#### **F. General Notification:**

##### **Agenda No. 33**

IEC code: 2017-47-DT-96

Type of submission: General Notification

Title of project: Investigation of Rheumatic AF Treatment Using vitamin K antagonists, rivaroxaban or aspirin Studies. (INVICTUS)

PI: Dr Sudeep Kumar

Department: Cardiology

Subject: SUSAR report dated 31 May 2022, period covered from 01-March-2022 to 31-May-2022 for review and notification.

Committee has noted.

##### **Agenda No. 34**

IEC code: 2020-196-DT-115

Type of submission: General Notification

Title of project: SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglycerase alfa) in India

PI: Dr Shubha Phadke

Department: Medical Genetics

Subject: Certificate of Insurance for IEC notification ( Policy No.: P0523200001/9999/100163 and Validity: 15 Jun 2022 to 14 Jun 2023).

Committee has noted.

##### **Agenda No. 35**

IEC code: 2020-196-DT-115

Type of submission: General Notification

Title of project: SHP669-406 :A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglycerase alfa) in India

PI: Dr Shubha Phadke

Department: Medical Genetics

Subject: Notification of study related documents ( Product Insert for VPRIV dated Feb 2019 and Product Insert for VPRIV dated Dec 2021).

Committee has noted.

##### **Agenda No. 36**

IEC code: 2020-331-DT-117

Type of submission: General Notification

Title of project: Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

PI: Dr Rajanikant R Yadav

Department: Radiodiagnosis

Subject: Updated Insurance for notification and approval (Insurance Policy Number:4067/101887722/02/000, Effective date: Jan 30, 2019 and Expiration date June 30, 2023).

Committee has noted.

##### **Agenda No. 37**

IEC code: 2020-331-DT-117

Type of submission: General Notification

Title of project: Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

PI: Dr Rajanikant R Yadav

Department: Radiodiagnosis

Subject: Investigator's Brochure's Version 5.0 for notification and approval.

Committee has noted.

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Any other:**

**Agenda No. 38**

**IEC: 2022-.....-EMP-128**

**Title of Project:** 'Training of in-service Clinicians from Government Hospitals' and 'Outreach Program for Aspirational Districts'

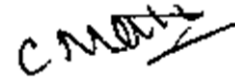
**PI:** Shubha Phadke

**Department:** Medical Genetics

The committee discussed that since this is a project related only to education and training of medical personnel's, it qualifies for 'Exemption from Review'.



(Dr. Vinita Agrawal)  
Member Secretary,  
IEC, SGPGI



(Dr. Chandishwar Nath)  
Chairman,  
IEC, SGPGI

**Dr. Col Varun Bajpai VSM**  
Executive Registrar  
SGPGIMS, Lucknow



## SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

**Minutes of the 124<sup>th</sup> Institutional Ethics Committee** meeting held on Saturday, 29<sup>th</sup> January 2022, at 10.30 am, through Telemedicine facility, SGPPI Lucknow using the licensed 'Zoom Cloud Meeting' platform. All members were communicated the meeting id. and password to join the virtual meeting through their devices.

### **Present:**

1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
2. Prof. Aneesh Srivastava, Dean, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Member
3. Justice S.C Verma, <i>Retd.</i> High Court Judge Allahabad -	Member
4. Shri. Vijai Varma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
5. Shri. Sharat Pradhan, Senior Journalist, (B-4, Dilkusha Colony, Lucknow	Member
6. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
7. Dr. Mohan Gurjar, Additional Professor, Department of CCM, S G P G I M S, Lucknow	Member
8. Prof. M. K. Mitra Former HOD Medicine, KGMU, Lucknow	Member
9. Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow	Member
10. Prof. V.L Bhatia, Prof. Department of Endocrinology, S G P G I M S, Lucknow	Member
11. Dr. Manuka Khanna, Prof. Department of Sociology, University of Lucknow	Member
12. Prof. A.K Srivastava, <i>Retd.</i> Prof. Department of Sociology, University of Lucknow	Member
13. Dr. Gautam Palit, Ex-Head, Div. of Pharmacology & Seni. Dep. Dir. & Medical Officer, CSIR-CDRI, Lko.	Member
14. Dr. S. Srivastava, <i>Retd.</i> Scientist-IV, Research Cell, S G P G I M S, Lucknow	Member
15. Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P G I M S, Lucknow	Member Secretary

Member Justice S C Verma, Mr Sharat Pradhan and Dean, Prof Aneesh Srivastava could not attend the meeting.

**Determination of quorum:** quorum was complete: 12 members present, with nine non-institutional members.

### **A: General discussions and confirmation of Minutes:**

The Chairman, Dr Chandishwar Nath, welcomed all members and greeted all in the New Year.

The members expressed their thanks to Prof MK Mitra who had joined the meeting from US even at midnight hours.

Chairman enquired about the status of SAE decisions. Mr Anand, Senior Administrative Officer, Bioethics Cell was asked to check with all members for their comments and send the decisions on SAE at the earliest.

**Disclosure of conflict of interest:** Chairman, called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting.

None of the members had any conflicts of interest.

**Reading and approval of the minutes of the last meeting** The Chairman presided over the discussion of the minutes of the 123rd IEC meeting held on 20<sup>th</sup> Nov. 2021. All members of the IEC approved the minutes.

### **B. Review of New Proposals:**

#### **Agenda No. 1**

**Type of submission:** Project Extramural

**IEC code:** 2021-302-EMP-124



**Title of project:** Autoantibody profile with genetic analysis for etiological categorization of Premature Ovarian Insufficiency

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Submit informed consent documents (participant information document-PID and consent form in Hindi.
2. Submit a copy of approval letter from the funding agency to the IEC.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 2**

**IEC code:** 2021-303-EMP-124

**Type of submission:** Project Extramural

**Title of project:** An open label Randomized, multi-centric trial to compare Efficacy and safety of Azathioprine with MycophenoLate Mofetil in immunologically low risk live donor renal allograft recipients (REALM)

**PI:** Dr Narayan Prasad

**Department:** Nephrology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. The primary reviewer and the committee members felt that the project was very valuable and useful. The positive results are likely to have important far-reaching repercussions for the welfare of Renal Transplant patients.

The committee has given the following suggestions to the PI:

1. Clarify the number of participants to be enrolled at SGPGIMS.
2. The drugs for the trial should be provided free of cost to the participants.
3. Submit Ethical committee clearance from other collaborative centers.
4. Hindi participant information document (PID); item no. 3 (Pg. 23), please rewrite. Do not convert the routinely used English words into incorrect Hindi words. (e.g. 'Graft' had been translated as 'Brashtachar')
5. English PID: The statement "MMF is costlier medicine and it has several side effects. The preferential use of AZA instead of MMF for maintenance immunosuppression would provide substantial cost saving, as well as comparable safety without affecting graft outcome" indicates conclusion of the study. Kindly delete.
6. Submit a copy of approval letter from the funding agency to the IEC.
7. Get CTRI before start of study.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 3**

**IEC code:** 2021-310-EMP-124

**Type of submission:** Project Extramural

**Title of project:** REduced duration of Eight versus twelve weeks of SOfosbuvir-VeLpatasvir in treatment naive non-cirrhotic patients with chronic hepatitis C virus infection: A Multicentric, Open labeled, Randomized, Non-inferiority trial (RESOLVE)

**PI:** Dr Amit Goel

**Department:** Gastroenterology

Primary reviewer (Technical): Prof. M. K Mitra

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. The primary reviewer and the committee members felt that the project was very valuable and useful. The positive results are likely to have important far-reaching repercussions for the welfare of Hepatitis C patients.

The committee has given the following suggestions to the PI:

1. Page two, proposal mention that 'interim analyses would be done when 33% and 67% sample size are completed, and Ethics Committee will be informed. However, on page 27, it is mentioned that 'interim analyses would be done when 50% of sample size is reached. Clarify.
2. Participant information document (PID); Item 4: Rewrite as '.....you are a patient of Hepatitis C and need treatment for this. We plan to evaluate the effectiveness of 12 weeks treatment vs 8 weeks treatment with the same combination of drugs, which has been approved by Ministry of Health, Government of India. According to Random sampling you will be taking the drugs for either 8 weeks or 12 weeks.'
3. PID for participants/ controls/ volunteers should not be separate.
4. Mention about blood collection in the PID.
5. Submit Ethical committee clearance from other collaborative centers.
6. Submit a copy of approval letter from the funding agency to the IEC.
7. Get CTRI before start of study.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 4**

**IEC code:** 2021-333-EMP-124

**Type of submission:** Project Extramural

**Title of project:** Assessment of patient-derived exosomal contents and computational analysis: Implication in early diagnosis, risk assessment for pancreaticobiliary cancer in India

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Dr Vinita Agrawal

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. The CV submitted for the fellow states that the Host Institute for the Ramalingaswamy Fellowship is AIIMS, Bhopal. Clarify
2. Participant information document (PID); point 6 states 'What will happen to me if I take part? Patients need to provide blood, urine, saliva and biopsy sample for assessment of disease. How will the patient give 'biopsy sample'? Modify the statement.
3. A co-PI from Surgical Gastroenterology should be included in the study for collection of biopsy samples.
4. Clarify the center where all the experiments will be conducted.
5. Mention the inclusion and exclusion criteria for controls. Submit PID for controls.
6. Submit a copy of approval letter of Ramalingaswamy Fellowship from the funding agency to the IEC.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 5**

**IEC code:** 2021-335-EMP-124

**Type of submission:** Project Extramural

**Title of project:** The impact of heart failure on household economic well-being'

**PI:** Dr Aditya Kapoor

**Department:** Cardiology

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Kindly clearly mention the nodal centers in the study.
2. Clarify the role of co-PI from Trivandrum.
3. Check Hindi participant information document (PID) for translations; volunteer should be 'pratibhagi' and not 'swayam sewak'.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 6**

**IEC code:** 2021-336-EMP-124

**Type of submission:** Project Extramural

**Title of project:** Evaluate the incidence of different phenotypes of neuropathic pain in cancer patients and compare the outcomes of pain based on the phenotypes after administration of anti-neuropathic medications. A Randomized parallel group trial.

**PI:** Dr Chetna Shamsbery  
Primary reviewer (Technical): Dr Mohan Gurjar  
Primary reviewer PID and CF: Dr A K Srivastava  
**Subject:** Project for review

**Department:** Anaesthesiology

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Please clarify about study design and primary outcome.
2. Please mention the details of the QST (Quantitative Sensory Test).
3. Please submit all pain scores/ scales being used in the study.
4. Please mention the role of two students in this study.
5. Please mention the title of the study and about randomization in the participant information document (PID). Simplify language of PID.
6. Submit a copy of approval letter from the funding agency to the IEC.
7. Get CTRI before start of study.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 7**

**IEC code:** 2021-341-EMP-124

**Type of submission:** Project Extramural

**Title of project:** A Prospective, Observational, Single Arm, Multicenter Registry to evaluate clinical outcomes of the Shockwave Coronary Intravascular Lithotripsy (IVL) followed by Stent Implantation in Calcified Coronary Arteries in Real World Indian Patient Population (S

**PI:** Dr Aditya Kapoor

**Department:** Cardiology

Primary reviewer (Technical): Dr Gautam Palit

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. The committee discussed that the legal expert should review the Clinical registry agreement and the insurance documents. The legal expert needs to check the documents for his opinion and decision communicated to the IEC and the PI.

The legal expert Mr Vijai Varma has given suggestions on CTA, the same has been included in comments to PI.

The committee has given the following suggestions to the PI:

1. Submit EC clearance document from collaborating centers.
2. Clearly mention the role of 'Translumina' in the study. What is the role of CRO?
3. Clarify the overlapping secondary endpoints (Pg. 5).
4. Clarify if it is a device trial. Submit IEC fees.
5. The CTRI does not mention the name of investigator from Lucknow.
6. Clarify; who will pay the compensation?
7. CTA: Jurisdiction is mentioned as New Delhi. It should be Lucknow.
8. CTA: should mention about Insurance cover.
9. CTA, Pg. 8, clause 10: the word 'direct damage' is not clear, which makes the entire sentence concerning liability of the sponsor confusing.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**Agenda No. 8**

**IEC code:** 2021-345-EMP-124

**Type of submission:** Project Extramural

**Title of project:** EUSTAR COHORT OF SYSTEMIC SCLEROSIS

**PI:** Dr Vikas Agarwal

**Department:** Clinical Immunology

Primary reviewer (Technical/PID & CF): Dr Surendra Srivastava

Primary reviewer PID and CF: Ms. Shalini Mathur

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify the age group of participants from SGPGI.
2. Clarify about the need of blood collection, investigations to be done and if samples will be sent abroad. If yes, submit material transfer agreement.
3. Kindly note that if samples are collected for future studies, it will require submission of the new project on these stored samples to the IEC for clearance.
4. One of the co-PI has resigned from the Institute; kindly make the required change in the list of co-PI's.
5. Please mention the role of 'Dr Oliver Distler' mentioned as PI.
6. Mention contact details of PI and bioethics cell in the participant information document (PID).
7. Submit a copy of invitation/approval letter from EUSTAR.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Member Secretary to review the correction made and clear the above project.

**Agenda No. 9**

**IEC code:** 2021-332-DM-124

**Type of submission:** Project DM/MCh/MD

**Title of project:** Improvement in endoscopic mucosal visibility using a pre-procedure combination drink of N-acetylcysteine and simethicone: A Randomized controlled trial

**PI:** Dr U C Ghoshal

**Department:** Gastroenterology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Dr A K Srivastava

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Clarify the role of 'Delvin Formulations Pvt. Ltd.'. This study is a company-sponsored study. Submit Clinical Trial Agreement (CTA), insurance certificate and IEC fees.
2. Please clarify if the combination formulation is available commercially in India or not? Provide necessary documents.
3. In participant information document (PID) (a) Need to mention that there is equal chance to get involved in the intervention arm as well as in the control arm (b)

- Mention Name and address of PI/Guide as well as Bioethics Cell/Member Secretary, IEC.
4. The statement 'We hope that the treatments will help you. However, this cannot be guaranteed.' is not required, as the study is related with a procedure not treatment.
  5. It is stated that 'The drug and the placebo will be provided by Delvin Formulations private limited' but placebo will not be used as clearly mentioned in methodology (section Comparator). Please clarify.
  6. In study protocol and PID: (a) Replace word subject with 'Participant' (b) Avoid word placebo
  7. Get CTRI before start of study.

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**Agenda No. 10**

**IEC code:** 2021-308-PDAF-124

**Type of submission:** Project PDAF

**Title of project:** Correlation between Vitamin D level and outcomes of Transforaminal Epidural Steroid Injection in Lumbar Radiculopathy : A Prospective open level Randomized Controlled Trial

**PI:** Dr Sanjay Kumar

**Department:** Anaesthesiology

Primary reviewer (Technical): Dr Mohan Gurjar

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. The members discussed that in patients whom Vit D deficiency has been found, it is not ethical to not to give Vit D supplementation. Therefore, a change in study design can be suggested.

The committee has given the following suggestions to the PI:

1. Mention method of randomization
2. One of the co-PI has superannuated from the Institute; kindly make the required change in the list of co-PI's.
3. In Group B: It is unethical not to prescribe Vit D supplements when the level is below 50 nmol/liter (20 ng/ml). Vit D supplements should be provided to all Vit D deficient patients of group A & B. Kindly change study design.  
Suggestion: There can be two groups – (A) Vit D deficient and (B) Vit D non-deficient. The base line pain score (prior to treatment), post treatment score and level of Vit D at the same time points in the patients should be compared between groups A and B. This design will also provide a correlation between Vit D level and improvement in pain relief. Within the group analysis (individual patient based) of group A can further indicate whether rise in Vit D level is linked to pain relief or not.
4. Please clarify the role of the student.
5. Participant information document (PID) should mention about (a) Randomization- there is equal chances for participant to get involved in the one of the groups (b) funding agency); wrongly mentioned as Institute (c) payment for extra visits, drugs and procedure to be clarified (d) Name and address of PI as well as Member Secretary, IEC.
6. Submit a copy of approval letter from the funding agency to the IEC.

7. Get CTRI before start of study.

**Decision:** Major Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**Agenda No. 11**

**IEC code:** 2021-342-DT-124

**Type of submission:** Project Drug/device trials

**Title of project:** Impact of use of oral nutritional supplement on physical health, mental health and immune health in growing children at risk of under nutrition.

**PI:** Dr P Bhattacharya

**Department:** General Hospital

Primary reviewer (Technical): Prof. V.L Bhatia

Primary reviewer Legal: Judge (Retd.) Vijai Varma

Primary reviewer PID and CF: Shri Sharat Pradhan

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed. The members discussed that this is a phase IV post-marketing study of an oral supplement (Prohance Junior). It was decided that the project should be sent for peer review to the Research committee or to external experts before any decision is taken, as the Departmental Committee at General Hospital comprises of specialists from unrelated branches.

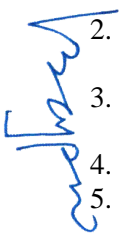
The committee has given the following suggestions to the PI:

1. The summary is not complete. It should clearly address the problem, criteria and methods to be followed.
2. It is not clear as to who will perform the developmental testing and IQ testing. Please clarify.
3. The Administrative Head of General Hospital should sign the certificate which is to be signed by the Head of the Department.
4. Kindly submit Ethical clearance from other centers.
5. CTA: The Sponsor, Sun Pharma, is not a party to the CTA, whereas there are obligations on its part. If it fails to discharge its duties and obligations, then the Institution will not be able to take action. Hence, it should be included as a party.
6. CTA: Cl.20 at page 10, the entire clause is quite confusing. Why PI should indemnify when there is no misconduct etc. on his part. Besides Cl.20 (e) is not at all proper where it is mentioned, 'Notwithstanding anything contained herein, the liability of the Sponsor will be limited to the Sponsorship amount paid to CRO'. This is totally unwarranted, as the indemnity amount cannot be limited merely to the amount paid for the Sponsorship to the CRO.
7. Insurance cover is until June 2022. It will require extension.
8. The study will need CTRI registration.

**Decision:** Major Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee will discuss the project again after peer review recommendations and submission of required documents.



**Agenda No. 12****IEC code:** 2021-346-DT-124**Type of submission:** Project Drug/device trials**Title of project:** A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease subcutaneous tissue.**PI:** Dr Kausik Mandal**Department:** Medical Genetics

Primary reviewer (Technical): Prof. Amita Panday

Primary reviewer Legal: Judge (Retd.) Vijai Varma

Primary reviewer PID and CF: Dr. Manuka Khanna

**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. SGPGI is not included in the approved list by DCGI. Please submit.
2. The name of SGPGI is not mentioned as a center in CTRI.
3. Submit proper informed consent documents (participant information document-PID and consent forms)
4. CTA: Sponsor has not been made a party though it has certain obligations to perform. If it fails to discharge its duties, whereby the conduct of the trial may be adversely affected, the Institute or the PI cannot take any action against the Sponsor. Sponsor needs to be arrayed as a party.
5. CTA: At page 3 in Cl.2, C(I), it is mentioned, 'Deleted intentionally'. Clearly mention what was deleted.
6. CTA: At page 22, pertaining to Assignment, it is mentioned that any assignment of the agreement by the PI or the Institution a prior written consent of the CRO or the Sponsor is required. However, there is no such requirement for the CRO/Sponsor. The Sponsor or the CRO should at least give a notice of any assignment by them to the Institution or The PI before making any such assignment lest they are caught unawares.
7. CTA: At page 20, pertaining to Insurance, in the Insurance details the total insurance coverage is shown as Rs.1,77,000 which is incorrect as it is the amount of premium and not the amount of coverage which is 2,00,00,000. Make the correction.
8. CTA: In Cl.20 and 21, the jurisdiction of the courts at Delhi is mentioned. It should be courts at Lucknow instead of Delhi.
9. CTA: In Cl 26, the seat of Arbitration should be Lucknow instead of Mumbai.

Dr. Col. Varun Bajpai VSM  
Executive Registrar  
SGPGIMS, Lucknow

**Decision:** Minor Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

**Agenda No. 13****IEC code:** 2021-347-DT-124**Type of submission:** Project Drug/device trials**Title of project:** A Prospective, Open-Label, Multicentered, Non-Randomized, Non-Comparative Active Post-Marketing Surveillance to test the safety and efficacy of Diperoxochloric Acid [DPOCL] topical solution in patients with diabetic neuropathic ulcers of skin and subcutan**PI:** Dr Gyan Chand**Department:** Endocrine Surgery

Primary reviewer (Technical): Prof. V.L Bhatia



Primary reviewer Legal: Judge (Retd.) Vijai Varma  
Primary reviewer PID and CF: Dr. Manuka Khanna  
**Subject:** Project for review

Scientific issues, ethical issues and informed consent documents were discussed.

The committee has given the following suggestions to the PI:

1. Submit proper methodology that will be followed by the PI at SGPGIMS. Mention inclusion and exclusion criteria.
2. It is a post marketing multicentric surveillance study. Name the other centers.
3. Sponsor mentioned in application and protocol is Centaur Pharmaceuticals Pvt. Ltd. However, Ayush licensing is for M/s. Datt Mediproducts Pvt. Ltd. The name of VELVERT is mentioned in CTRI; is it a Centaur Pharma product or from Datt Mediproducts? Please clarify.
4. Submit copy of marketing permission from Regulatory authorities.
5. Mention rationale of including 250 controls.
6. CTRI number is pending. Please submit.
7. The index of the project submitted is chaotic. Kindly ensure that all documents are arranged in proper order in future submissions.

**Decision:** Major Modification.

PI advised to submit above correction within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Committee authorized the Expedite Review Committee to review the correction made and clear the above project.

### **C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee:**

**The recommendation of the Member Secretary/3-Member Committee/Expedite Review Committee (EXP meeting no. 43, agenda 14-24 and for clarifications submitted by the PI in agenda no. 25-26) who has given clearance for the proposals has been approved by the committee.**

#### **Agenda No. 14**

**IEC code:** 2021-251-DM-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Comparison of the effect of chest percussion and expiratory rib cage compression on blood gases and static lung compliance in mechanically ventilated adult patients with acute respiratory distress syndrome: A randomized crossover study

**PI:** Dr Mohan Gurjar

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 15**

**IEC code:** 2021-256-IMP-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Expression of mismatch repair (MMR) protein in glioma

**PI:** Dr Sushila Jaiswal

**Department:** Pathology

**Subject:** Expedite review project for IEC notification

#### **Agenda No. 16**

**IEC code:** 2021-258-IMP-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Quantitative And Qualitative Assessment Of RNA From Archived FFPE Tissues To Investigate Its Suitability For Next Generation Sequencing.

**PI:** Dr Raghavendra L

**Department:** Pathology

**Subject:** Expedite review project for IEC notification

**Agenda No. 17**

**IEC code:** 2021-260-IMP-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Incidence and Prognostic Significance of Programmed Death Ligand-1 (PD-L1) Expression in Thyroid Carcinoma of Follicular Origin

**PI:** Dr Anjali Mishra

**Department:** Endocrine Surgery

**Subject:** Expedite review project for IEC notification

**Agenda No. 18**

**IEC code:** 2021-264-DM-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Incidence and clinical implication of neck and limb deep vein thrombosis in a multidisciplinary ICU –A prospective observational study

**PI:** Dr Afzal Azim

**Department:** Critical Care Medicine

**Subject:** Expedite review project for IEC notification

**Agenda No. 19**

**IEC code:** 2021-267-PDCC-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Outcome of pubertal induction by gonadotropins: a retrospective study

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

**Subject:** Expedite review project for IEC notification

**Agenda No. 20**

**IEC code:** 2021-272-IP-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Mammographic characteristics of granulomatous and non-granulomatous inflammation in breast and utility of Digital breast tomosynthesis

**PI:** Dr Namita Mohindra

**Department:** Radiodiagnosis

**Subject:** Expedite review project for IEC notification

**Agenda No. 21**

**IEC code:** 2021-276-IMP-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Study of Programmed Death Ligand-1 (PDL-1) Expression and its Role as a Predictive Biomarker in Esophageal Carcinoma

**PI:** Dr Pallavi Prasad

**Department:** Pathology

**Subject:** Expedite review project for IEC notification

**Agenda No. 22**

**IEC code:** 2021-284-MCh-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Long term response to alpha blockers in Primary Bladder Neck Obstruction in males: The search of a reliable predictor

**PI:** Dr Sanjoy Kumar Sureka

**Department:** Urology

**Subject:** Expedite review project for IEC notification

**Agenda No. 23**

**IEC code:** 2021-285-MCh-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Outcomes of smiley cutaneous ureterostomy as a urinary diversion during radical cystectomy in patients with advanced bladder cancer

**PI:** Dr Sanjoy Kumar Sureka

**Department:** Urology

**Subject:** Expedite review project for IEC notification

**Agenda No. 24**

**IEC code:** 2021-286-PDCC-EXP-43

**Type of submission:** Expedite review project for IEC notification

**Title of project:** Outcomes of two core TRUS guided prostatic biopsy in metastatic prostatic cancer patients with PSA>75 ng/ml

**PI:** Dr Sanjoy Kumar Sureka

**Department:** Urology

**Subject:** Expedite review project for IEC notification

**Agenda No. 25**

**IEC code:** 2021-248-IP-123

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Analgesic efficacy of Proximal Adductor Canal Block supplemented with Genicular Nerve Block for post-operative analgesia following Anterior Cruciate Ligament Reconstruction: A Prospective Randomised Single Blind Two Arm Parallel Study.

**PI:** Dr Vansh Priya

**Department:** Anaesthesiology

**Subject:** Clarification submitted by Dr Vansh Priya Dept. of Anaesthesiology and approved by Member Secretary for notification

**Agenda No. 26**

**IEC code:** 2021-249-IP-123

**Type of submission:** Reporting decisions of 3 Member Committee/Member Secretary

**Title of project:** Posterior Transversus Abdominis Plane Block versus Fascia Transversalis Plane Block for post-operative analgesia following unilateral open inguinal hernia repair: A Prospective, Randomised, Single Blind, Two Arm Parallel Study.

**PI:** Dr Vansh Priya

**Department:** Anaesthesiology

**Subject:** Clarification submitted by Dr Vansh Priya Dept. of Anaesthesiology and approved by Member Secretary for notification

**D. Notification for Amendments/Addendum:**

**Agenda No. 27**

**IEC code:** 2019-108-IMP-109

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** Study of 24 hours glucose profile in patients with gestational diabetes

**PI:** Dr Preeti Dabadghao

**Department:** Endocrinology

**Subject:** Notification of Amendment ( Inclusion criteria and Exclusion criteria).

**Committee has noted and granted approval.**

**Agenda No. 28**

**IEC code:** 2021-178-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Notification of Amendment (Amended Protocol Version No. V00-IN.01 and Protocol signature page).

**Committee has noted. Kindly submit DCGI approval.**

**Agenda No. 29**

**IEC code:** 2021-179-DT-121

**Type of submission:** Notification of Amendments/Addendum

**Title of project:** A multicenter, single-arm, open label trial to evaluate efficacy and safety of oral, twice daily LNP023 in adult aHUS patients who are naïve to complement inhibitor therapy

**PI:** Dr DS Bhadauria

**Department:** Nephrology

**Subject:** Clinical trial protocol (version No. 00-IN.01 dated 06-Dec-2021)

**Committee has noted. Kindly submit DCGI approval.**

**F. General Notification:**

**Agenda No. 30**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Investigator Brochure Edition-5 related documents for IEC notification.

**Committee has noted.**

**Agenda No. 31**

**IEC code:** 2020-286-DT-116

**Type of submission:** General Notification

**Title of project:** A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE DOSE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VIS649 IN PATIENTS WITH INNUNOGLOBULIN A(IgA) NEPHROPATHY

**PI:** Dr Narayan Prasad

**Department:** Nephrology

**Subject:** Referring Physician related documents for IEC notification.

**Committee has noted.**

**Agenda No. 32**

**IEC code:** 2020-331-DT-117

**Type of submission:** General Notification

**Title of project:** Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperable Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV Clinical Trial

**PI:** Dr Rajanikant R Yadav

**Department:** Radiodiagnosis

**Subject:** IEC notification of Investigator's Brochure version 3.0 and version 4.0.

**Committee has noted.**

**H. Study Final/Annual/Progress reports /Close out Notification:**

**Agenda No. 33**

**IEC code:** 2019-30-IP-108

**Type of submission:** Final/Annual/Progress reports

**Title of project:** A randomized study of Consolidation Chemoradiation versus Observation after first line Chemotherapy in Locally Advanced Carcinoma Gallbladder

**PI:** Dr Sushma Agrawal

**Department:** Radiotherapy

**Subject:** Annual progress reporting date 12.01.2022 and study is ongoing and the accrual is slow due to COVID, PI request for extend the validity of the above mentioned study until 30.6.23.

**Committee has noted and granted approval.**

**Agenda No. 34**

**IEC code:** 2019-62-DM-EXP-7

**Type of submission:** Study Close out Notification

**Title of project:** Role of CD 64 in diagnosis of bacterial infection in children with decompensated chronic liver disease and effect of infection on coagulation

**PI:** Dr Anshu Srivastava

**Department:** Ped. Gastroenterology

**Subject:** Study Completion report (Date of termination: 07/10/2021).

**Committee has noted.**

**Agenda No. 35**

**IEC code:** 2021-80-DT-119

**Type of submission:** Study Close out Notification

**Title of project:** Phase 3 Study to Evaluate the Efficacy and Safety of Subcutaneous Marzeptacog Alfa (Activated) For On-Demand Treatment and Control of Bleeding Episodes in Subjects with Hemophilia A or Hemophilia B, with Inhibitors: The Crimson 1 Study

**PI:** Dr Shubha Phadke

**Department:** Medical Genetics

**Subject:** Premature termination report (Date of termination: 15-Nov-2021).

**Committee has noted.**

(Dr. Vinita Agrawal)  
Member Secretary,  
IEC, SGPGI

(Dr. Chandishwar Nath)  
Chairman,  
IEC, SGPGI