

CIRCULAR

Sub: Minutes of Eighth Meeting of Institute Ethics Committee (Human Studies) - Reg.

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The Eighth Meeting of Institute Ethics Committee (Human Studies) was held on 30-10-2014 and 31-10-2014 in the PGDPHM Seminar Hall, IV Floor, Preventive and Social Medicine Department, Administrative Block, JIPMER, under the chairmanship of Mr. E.V. Kumar, Chief Justice (Retd.), Union Territory of Puducherry. The meeting was attended by Dr. S.C. Parija, Dean Research (Vice Chairman), Dr. T.K. Dutta (Member Secretary), Dr. Vasantha Muthuswamy (Member), Dr. M.G. Sridhar (Member), Dr. Vikram Kate (Member), Dr. K. Chandrashekar (Member), Dr. Medha R. (Member) and Dr. S. Sandhiya (Member).

The meeting started at 9.00 AM with welcome address by the chairman Mr. E.V. Kumar. Following this, the Member Secretary, briefed the proceedings of the day and requested the Chairman to take over the session. Before starting the presentation of proposals, the chairman raised concern regarding the modification of the existing consent forms and this was supported by Dr. Vasantha Muthuswamy. She added that references need to be included in the protocol and mentioned that blanket consent needs to be approved as per ICMR ethical guidelines for biomedical research in Human Participants (2006). In addition she said that serious adverse events (SAE) reported to IEC can be discussed in subcommittee and the report needs to be submitted to IEC main committee. She also suggested on constituting SAE committee as per the rules of Govt of India to help the IEC for taking decisions on the SAE reported to IEC. In addition she mentioned that, till such a committee is formed, Dept of Clinical Pharmacology can be approached for getting opinion regarding SAEs reported to IEC.

Dr. Sridhar suggested on outsourcing translation of English consent forms while Dr. Zile Singh reminded regarding submission of annual report of the ongoing projects. Dr. Chandrasekaran insisted on taking insurance for IEC members. The Vice Chairman said that it is mandatory for the Guide to be present for the student proposals. Chairman suggested on obtaining consent from spouse of the participant for studies related to assessment of DNA.

The committee agreed on Dr. Vasantha Muthuswamy's suggestion that any study involving data, samples and identity of patient is not revealed can be taken up by subcommittee for expedited review, even if it includes special or vulnerable populations. Further she added that systematic reviews and metanalysis need not be reviewed by IEC. She also suggested on having SOPs for each function of IEC as per ICMR and FERCI guidelines to obtain national as well as international accreditations. Dr. Parija stated that in principle the IEC accepts the suggestion and will take effort towards achieving accreditation for JIPMER IEC.

During the meeting a total of 92 proposals were discussed and after deliberation the following decisions were arrived at

- **Number of proposals approved** : 4
- **Number of proposals approved subject to minor corrections** : 73
- **Number of proposals to be resubmitted** : 7
- **Number of proposals for which investigator/ Guide was absent** : 8

Dr. Medha R. opted out of the discussion for the following proposals: JIP/IEC/2014/8/364, JIP/IEC/2014/8/389, JIP/IEC/2014/8/400, JIP/IEC/2014/8/414, JIP/IEC/2014/8/415. Dr. Sandhiya opted out of the discussion for the proposals JIP/IEC/2014/8/409 and JIP/IEC/2014/8/442. At the end of presentations, Chairman and Member Secretary thanked all the members and concluded the session.

Instructions to be followed during submission:

The investigators whose proposals need modifications are required to send one copy of revised proposal along with CD and a copy of original proposal to Dr. T.K. Dutta, Member-Secretary on or before 20-11-2014. Please follow the IEC format in the revised protocols and highlight the changes with a yellow highlighter. Kindly submit corrected protocol with both English and Tamil consent forms stapled together. Protocols and consent forms submitted separately will not be considered for approval process. In addition, the candidates need to submit a covering letter enumerating the comments from the IEC minutes for their proposal, with point to point mention of where the revision has been highlighted.

The proposals can be submitted in **Institute Ethics Committee room** (Room No: 101, opposite to DDA's room, 1st floor, Administrative Block) between 3.30 – 4.30 pm from Monday to Friday. If the revision is satisfactory, the approval certificate will be issued after consulting the subcommittee. Otherwise, they need to submit 15 copies of proposal (Form 1A) to IEC for its approval and it will be considered as fresh proposal.

Fresh proposals can also be submitted in **Institute Ethics Committee room** between 3.30 – 4.30 pm from Monday to Friday. All the fresh projects submitted on or before 10th of each month will be taken up for that month's ethics committee meeting.

For student projects, the guide should give a signed statement on a separate sheet with details of project proposal that **"I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me."**

Recommendations of the committee for the presented research projects is as given below:

Sl.No	Re. No.	Names of Investigators and Co-investigators	Title of the Research Projects	Recommendations
1	JIP/IEC/2014/8/355	Investigator: Dr. Vidhya Meena. S, Junior Resident, Anatomy Guide: Dr. Sarasu. J, Associate Professor, Anatomy Co-Guides: Dr. Sasirekha. R, Associate Professor, Obstetrics & Gynecology Dr. Shewade. D.G, Professor, Pharmacology	Assessment of fetal DNA in maternal plasma as a marker in early detection of preeclampsia	<u>Approved subject to following corrections:</u> <ul style="list-style-type: none"> • Clarify regarding compensation, research related injury, unforeseeable injury. • Mention compensation will be provided in terms of free medical treatment. • Clarify on future storage of samples. • Only subjects >18 years of age will be included in the study • Tamil consent form needs to be in concurrence with English consent form. • Change the level of risk to "Minimal risk". • Mention the risks involved during blood collection. • Use same consent forms for both

				controls and cases.
2	JIP/IEC/2014/8/356	<p>Investigator: Dr. Amruta Nirale, Junior Resident, Anaesthesiology and Critical Care</p> <p>Guide: Dr. Sandeep Kumar Mishra, Associate Professor, Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Prasanna Udupi Bidkar, Associate Professor, Anaesthesiology and Critical Care</p>	Comparison of effect of pneumoperitoneum and peep on oropharyngeal sealing pressure with ambu aura gain and proseal lma in gynecological laproscopic surgery:a randomised controlled trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention the level of risk as “More than minimal risk”. • Compensation needs to be paid if foreseeable or unforeseeable risk occurs as per JIPMER guideline. • Free treatment needs to be given as per JIPMER guideline. • Remove the clause on storage of samples and possible future use of stored biological samples. • Tamil consent form needs to be in concurrence with English consent form. • Mention confidentiality will be maintained during publication of results. • Mention records will be stored for 3 years.
3	JIP/IEC/2014/8/357	<p>Investigator: Dr. Ramya R, Junior Resident, Anaesthesiology and Critical Care</p> <p>Guide: Dr. Ashok Shankar Badhe, Professor, Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Mohan V K, Assistant Professor, Anaesthesiology and Critical Care</p>	Comparison of weight based and pinna size based selection of Proseal laryngeal mask airway (PLMA) in paediatric age group in controlled ventilation under General Anaesthesia	Absent
4	JIP/IEC/2014/8/358	<p>Investigator: Dr. Thooyamani. P, Junior Resident, Anaesthesiology and Critical Care</p> <p>Guide: Dr. Pankaj Kundra, Professor and Head, Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Priya Rudingwa, Assistant Professor, Anaesthesiology and Critical Care Dr. Gopalakrishnan. S, Professor, ENT</p>	Comparison of success of intubation and laryngeal morbidity in Bougie versus Wire guided intubation	Absent
5	JIP/IEC/2014/8/359	<p>Investigator: Dr. Rashmi.C, Junior Resident, Anaesthesiology and Critical Care</p> <p>Guide: Dr. S. Adinarayanan, Associate Professor, Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Srinivasan Swaminathan, Assistant Professor, Anaesthesiology and Critical Care</p>	Comparison of dexamethasone and dexmedetomidine as adjuvants to bupivacaine in prolonging the duration of single injection supraclavicular brachial plexus block	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Resubmission of IEC Consent forms as per JIPMER format • Mention the level of risk as “More than minimal risk”. • Clarify on inclusion of age group in both English and Tamil consent forms. • Tamil consent form needs to be in concurrence with English consent form. • Under methodology mention clearly how randomization and double blinding will be done. • Include signature of investigators in ICF-2 • Simple language needs to be used in the

				<p>consent forms.</p> <ul style="list-style-type: none"> • Use of placebo needs to be justified
6	JIP/IEC/2014/8/360	<p>Investigator: Dr. Eeswary, Junior Resident, Anaesthesiology & Critical Care</p> <p>Guide: Dr. A. Vasudevan, Additional Professor, Anaesthesiology & Critical Care</p> <p>Co-Guide: Dr. Satyen Parida, Associate Professor, Anaesthesiology & Critical Care</p>	<p>Comparison of 'Propofol-Ketamine anaesthesia without airway device' and 'Sevoflurane based balanced anaesthesia using Laryngeal Mask Airway' for catheter-based cardiac procedures in children: A Randomized Clinical Trial</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Resubmission of IEC Consent forms as per JIPMER format • Simple language needs to be used in the consent forms • Mention the level of risk as “Minimal risk”. • Mention “confidentiality of your wards will be maintained during publication of results”. • Mention records will be stored for 3 years. • Parent / LAR consent form and assent forms needs to be modified. • Tamil consent form needs to be in concurrence with English consent form.
7	JIP/IEC/2014/8/361	<p>Investigator: Dr. Milthi Manoj, Junior Resident, Anaesthesiology and Critical care</p> <p>Guide: Dr. Satya Prakash M .V .S, Associate Professor, Anaesthesiology and Critical care</p> <p>Co-Guide: Dr. Srinivasan Swaminathan, Assistant Professor, Anaesthesiology & Critical Care</p>	<p>Comparison of Ease of Administration of Intranasal Midazolam Spray and Oral Midazolam Syrup by Parents as Premedication to Children Undergoing Elective Surgery</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • ICF-2 needs to be tailor-made for this study by including a phrase stating that the parents/LAR understand and agree to follow the instructions of the Investigator. • Mention the level of risk as “Minimal risk”. • Mention records will be stored for 3 years. • Numbering of paragraphs in English consent form needs to be corrected. • Clarify on clause of storage of data and biological samples. • Tamil consent forms needs to corrected. • Simple language needs to be used in the consent forms
8	JIP/IEC/2014/8/362	<p>Investigator: Dr. Mamatha Munaf, Junior Resident, Anaesthesiology and Critical Care</p> <p>Guide: Dr. Hemavathi Balachander, Professor, Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Chitra Rajeswari T, Assistant Professor, Anaesthesiology and Critical Care</p>	<p>Effect of intra operative CPAP on the postoperative pulmonary function in overweight patients undergoing surgeries under spinal anaesthesia</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Methodology needs to be explained clearly. • Remove the clause on DCGI approval. • Clarify on clause of storage of data and biological samples. • Clarify regarding compensation for participation • Simple language needs to be used in the consent forms • Remove “Name” from the list of variables in the protocol
9	JIP/IEC/2014/8/363	<p>Investigator: Dr. Ranjana.V, Junior Resident, Anesthesiology & Critical Care</p> <p>Guide: Dr. Anusha Cherian, Assistant Professor, Anaesthesiology &</p>	<p>Comparison of intraoperative gas composition while using low flow anaesthesia with and without nitrous oxide</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Expand the abbreviations in the protocol. • Consent form needs to be resubmitted as per JIPMER IEC format. • Mention confidentiality will be maintained during publication of results.

		Critical Care Co-Guide: Dr. Sakthirajan, Assistant Professor, Anaesthesiology & Critical Care		<ul style="list-style-type: none"> • Mention records will be stored for 3 years. • Signature of investigator needs to be added. • Mention free treatment will be given as per JIPMER guidelines.
10	JIP/IEC/2014/8/364	Investigator: Dr. Ramesh Panga, Junior Resident, Anaesthesiology and Critical Care Guide: Dr. Satyen Parida, Associate Professor, Anaesthesiology and Critical Care Co-Guides: Dr. Medha R., Associate Professor, Biochemistry Dr. Pankaj Kundra, Professor & Head, Anaesthesiology and Critical Care	Study of glutathione-s-transferase levels in patients receiving intravenous paracetamol perioperatively – A randomized clinical trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Mention the duration and frequency of follow up in the protocol and the consent forms. • Methodology needs to be explained in simple language.
11	JIP/IEC/2014/8/365	Investigator: Dr. Dhanyasi Shrvanalakshmi, Junior Resident, Anesthesiology and Critical Care Guide: Dr. Prasanna Udupi Bidkar, Associate professor, Anesthesiology and Critical Care	Comparison of tracheal intubation using King Vision and C-MAC videolaryngoscopes in patients with cervical spine immobilization	Approved subject to following corrections: <ul style="list-style-type: none"> • Change the level of risk to “Minimal risk”.
12	JIP/IEC/2014/8/366	Investigator: Dr. Ranjith Kumar.S, Junior Resident, Anesthesiology and Critical Care Guide: Dr. P. Sakthirajan, Assistant Professor, Anesthesiology and Critical Care Co-Guides: Dr. Anusha Cherian, Additional Professor, Anesthesiology and Critical Care Dr. Jagdish Menon, Professor and Head, Orthopedics	Dexmedetomidine as an Adjunct to Bupivacaine in Ultrasound Guided Fascia Iliaca Compartmental Block for Femur Surgeries: A Randomized Controlled Trial	Absent
13	JIP/IEC/2014/8/367	Investigator: Dr. Angel Mercy Sylus, Junior Resident, Biochemistry Guide: Dr. H. Nandeesh, Assistant Professor, Biochemistry Co-Guides: Dr. T. Chitra, Assistant Professor, Obstetrics and Gynaecology Dr. M. G. Sridhar, Senior Professor, Biochemistry	Effect of clomiphene citrate on nitric oxide matrix metalloproteinase-9 and interleukin-10 in women with polycystic ovary syndrome	Approved subject to following corrections: <ul style="list-style-type: none"> • Clarify regarding storage of samples. • Remove the sentence that records will be stored indefinitely and change it to “records will be stored for a period of 3 years”. • Mention duration of study as 3 wks. • Avoid using medical jargon in the consent forms, which needs to be written in simple language.
14	JIP/IEC/2014/8/368	Investigator:	Evaluation of soluble	Approved subject to following corrections:

		<p>Ms. S. Suganya, II Yr M.Sc Medical Biochemistry, Biochemistry</p> <p>Guide: Dr. R. Soundravally, Associate Professor, Biochemistry</p> <p>Co-Guides: Rahul Dhodapkar, Associate Professor, Microbiology Dr. T. Kadhiravan, Associate Professor, Medicine Dr. P.Narayanan, Associate Professor, Pediatrics</p>	CD70 for their prognostic role in dengue viral infection	<ul style="list-style-type: none"> • Mention clearly the total number of samples that will be taken during the study period, both in the protocol as well as the consent forms for the cases and the controls. • Mention the level of risk as “Minimal risk”. • Clarify on storage of samples. • English and Tamil consent forms needs to be in concordance. • Mention records will be stored for a period of 3 years. • Mention the duration of study as 7 days. • Clarify regarding provision of compensation for participation. • Please include separate assent form for children > 7 years of age.
15	JIP/IEC/2014/8/369	<p>Investigator: Dr. Debadyuti Sahu, Biochemistry</p> <p>Guide: Dr. R. Soundravally, Associate Professor, Biochemistry</p> <p>Co-Guides: Rahul Dhodapkar, Associate Professor, Microbiology Dr. T. Kadhiravan, Associate Professor, Medicine Dr. P.Narayanan, Associate Professor, Pediatrics</p>	Assessment of matrix metalloproteinases and their inhibitor as prognostic markers in Dengue Viral Infection	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Please include separate consent form for controls. • Please include separate assent form for children > 7 years of age. • Clarify on storage of samples. • Mention records will be stored for a period of 3 years. • Mention regarding sample calculation under methodology. • Mention the study design as prospective longitudinal study.
16	JIP/IEC/2014/8/370	<p>Investigator: Ms. Aswathy J.S, II, M.Sc. (Medical Biochemistry), Biochemistry</p> <p>Guide: Dr. Prashant S. Adole, Assistant Professor, Biochemistry</p> <p>Co-Guides: Dr. Mukta Wyawahare, Associate Professor, Medicine; Dr. Rama Prakasha S, Assistant Professor, EM & Trauma</p>	Assessment of serum vaspin level among type 2 diabetes mellitus patients with and without acute coronary syndrome	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Clarify regarding storage of samples. • If patient is not stable, consent will be obtained from LAR first and then from the patient, after he/she stabilizes.
17	JIP/IEC/2014/8/371	<p>Investigator: Dr. M. Hadar Basha, Junior Resident, Emergency Medicine and Trauma</p> <p>Guide: Dr. S. Jagdish, Professor, General Surgery and Head, Emergency Medicine and Trauma</p> <p>Co-Guide: Dr. Swaroop Kumar Sahu, Assistant Professor, Preventive and Social Medicine</p>	Magnitude and Profile of assault injuries attending Department of Emergency Medicine and Trauma.	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention regarding the ethical issues involved. • Signature of Guide and co-guide needs to be obtained. • Clarify on expected benefits to the study participant. • Mention that patient is free to withdraw from the study without assigning any reasons. • Mention compensation will be provided for disability or death as per JIPMER guidelines. • Medical superintendent needs to be

				<p>informed about this study as it is being done in medico legal cases.</p> <ul style="list-style-type: none"> Care should be taken to avoid deviation from information given in MLC record.
18	JIP/IEC/2014/8/372	<p>Investigator: Dr. Archana Waganekar, Junior Resident, Emergency Medicine & Trauma</p> <p>Guide: Dr. S. Jagdish, Professor, Surgery, HOD, Emergency Medicine & Trauma</p> <p>Co-Guides: Dr. Sathia Prabhu A, Assistant Professor, Neurosurgery Dr. Harichandrakumar K T, Lecturer, Biometrics and Informatics</p>	Computed Tomography Profile and Its Utilization in Head Injury Patients in Emergency Department	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention consent will be taken from LAR or Medical Superintendent if unconscious patients are included in the study. In such patients re-consent needs to be taken after the patient regains consciousness. Consent form needs to be resubmitted with appropriate answers.
19	JIP/IEC/2014/8/373	<p>Investigator: Dr. Nair Santoshkumar Tangappan, Junior Resident, Department of Emergency Medicine and Trauma</p> <p>Guide: Dr. Vinay R. Pandit, Additional Professor, Emergency Medicine and Trauma</p> <p>Co-Guides: Dr. Nanda Kishore Maroju, Associate Professor, General Surgery Mr. K.T. Harichandrakumar, Lecturer, Medical Biometrics and Informatics</p>	Utility of Shock Index for predicting early mortality in patients of severe trauma.	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention consent will be taken from LAR or Medical Superintendent if unconscious patients are included in the study. In such patients re-consent needs to be taken after the patient regains consciousness. Mention the level of risk as “Minimal risk”. Consent form needs to be resubmitted with appropriate answers. Remove the clause on storage of samples and possible future use of stored biological samples. Tamil consent form needs to be in concurrence with English consent form. Mention confidentiality will be maintained during publication of results. Mention records will be stored for 3 years. Title needs to be changed and PGRMC to be informed.
20	JIP/IEC/2014/8/374	<p>Investigator: Dr. Jadhav Dhiraj Ramdas, Junior Resident, Emergency Medicine</p> <p>Guide: Dr. Vinay R. Pandit, Additional Professor, Emergency Medicine and Trauma</p> <p>Co-Guide: Dr. Santhosh Satheesh, Additional Professor and Head, Cardiology</p>	ST Segment Elevation Myocardial Infarction in Emergency Department	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention consent will be taken from LAR if unconscious patients are included in the study. In such patients re-consent needs to be taken after the patient regains consciousness. Tamil consent form needs to be in concurrence with English consent form. Mention confidentiality will be maintained during publication of results. Mention records will be stored for 3 years. Remove the clause on storage of samples and possible future use of stored biological samples. Mention that patient is free to withdraw from the study without assigning any reasons.

				<ul style="list-style-type: none"> Mention compensation will be provided for disability or death as per JIPMER guidelines.
21	JIP/IEC/2014/8/375	<p>Investigator: Dr. Rinoop Ramachandran, Junior Resident, Emergency Medicine</p> <p>Guide: Dr. S. Jagdish, Professor, Emergency Medicine</p> <p>Co-Guide: Dr. A. Ramesh, Associate Professor, Radiology</p>	Diagnostic Power of Focused Assessment with Sonography in Trauma (FAST) in Blunt Abdominal Trauma	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention confidentiality will be maintained during publication of results. Mention records will be stored for 3 years. Remove the clause on storage of samples. Mention consent will be taken from LAR or Medical Superintendent if unconscious patients are included in the study. In such patients re-consent needs to be taken after the patient regains consciousness. Include assent form for children > 7 yrs and < 18 years. Procedure needs to be included under methodology.
22	JIP/IEC/2014/8/376	<p>Investigator: Dr. Anandhi, Junior Resident, Emergency Medicine</p> <p>Guide: Dr. Vinay R. Pandit, Additional Professor, Emergency Medicine and Trauma</p> <p>Co-Guide: Dr. Kadhiraan, Associate Professor, Medicine</p>	Cardiac Arrhythmias, Electrolyte Abnormalities and Serum Cardiac Glycoside Concentrations in Yellow Oleander Poisoning	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention consent will be taken from LAR or Medical Superintendent if unconscious patients are included in the study. In such patients, re-consent needs to be taken after the patient regains consciousness. Mention level of risk as 'Minimal risk'. Mention clearly in methodology how cardiac glycosides and QT interval will be measured. Clarify regarding storage of biological samples.
23	JIP/IEC/2014/8/377	<p>Investigator: Dr. T. Saranya, Junior resident, ENT</p> <p>Guide: Dr. Sunil Kumar Saxena, Professor and HOD, ENT</p>	Comparative study of laser tonsillectomy with dissection tonsillectomy-randomised controlled clinical trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention the duration of participation in the study. Include parental / LAR consent form for children < 7 yrs. Include parental / LAR consent form for children > 7 yrs along with assent form. Mention level of risk as 'More than minimal risk'. Tamil consent form needs to be in concurrence with English consent form.
24	JIP/IEC/2014/8/378	<p>Investigator: Dr. Gerard Pradeep Devnath S, Forensic Medicine & Toxicology</p> <p>Guide: Dr. Ambika Prasad Patra, Assistant Professor, Forensic Medicine & Toxicology</p> <p>Co-Guides: Dr. Vinod Ashok Chaudhari, Assistant Professor, Forensic Medicine & Toxicology Dr. Zachariah Bobby,</p>	Estimation of death interval from biochemical analysis of vitreous humour and synovial fluid	<p>To be resubmitted with the following corrections:</p> <ul style="list-style-type: none"> Consent form needs to be submitted in JIPMER IEC format as waiver is not granted.

		Professor & Head, Biochemistry		
25	JIP/IEC/2014/8/379	Investigator: Dr Preetham Reddy, Junior Resident, Medicine Guide: Dr.Chanaveerappa Bammigatti, Associate Professor, Medicine Co-Guides: Dr R P Swaminathan, Professor and Head, Medicine Dr. Nandeesh Hanumanthappa, Assistant professor, Biochemistry	Serum procalcitonin levels in patients with snake bite induced cellulitis	Approved subject to following corrections: <ul style="list-style-type: none"> Assent forms to be included for children > 7 yrs age. The study needs to be mentioned as a diagnostic interventional study as procalcitonin level is measured. Mention compensation will not be provided for participation. Mention free treatment will be provided for research related injury, foreseeable and unforeseeable risks. Mention samples will not be stored for future purposes. Please correct typos in the protocol.
26	JIP/IEC/2014/8/380	Investigator: Dr. Radhakrishna Pedapati, Junior Resident, General Medicine Guide: Dr. Vinod KV, Associate Professor, General Medicine Co-Guide: Dr. Swaminathan RP, Senior Professor and Head, Medicine	Comparison of fasting plasma glucose, oral glucose tolerance test and hemoglobinA1c for diagnosis of diabetes mellitus in high risk subjects	Absent
27	JIP/IEC/2014/8/381	Investigator: Dr. Pavan kumar Rudrabhatla, Junior Resident, Medicine Guide: Dr. Deepanjali S, Assistant Professor, Medicine Co-Guide: Dr. R P Swaminathan, Senior Professor and HOD, Medicine Dr. Jharna Mandal, Associate Professor, Microbiology	Comparison of 7 days versus 14 days antibacterial treatment for hospitalized non-severe acute pyelonephritis patients – a randomized controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> Mention patient voluntarily and freely gives consent for participation. Mention that records will be preserved for 3 years. Mention free treatment will be provided as per JIPMER guidelines. Mention confidentiality will be maintained while analysis, presentation and publication of results. Mention the risks involved due to the use of antibiotics. Methodology needs to be completely explained. Sample size calculation needs to be included in the protocol.
28	JIP/IEC/2014/8/382	Investigator: Dr. Gopisree Peringeth, Junior Resident, Medicine Guide: Dr. R.P. Swaminathan, Senior Professor and Head, Medicine Co-Guides: Dr. Biswajit Dubashi, Associate Professor, Medical Oncology Dr. Pazhanivel Mohan, Assistant Professor, Medical Gastroenterology	Comparison of Efficacy of Hepatitis B Vaccination during Induction versus Maintenance Phase of Chemotherapy in Acute Lymphoblastic Leukemia – A Randomised Clinical Trial	To be resubmitted with following corrections: <ul style="list-style-type: none"> Resubmit the protocol and the consent forms with details regarding the maintenance phase. Change the level of risk as “minimal risk”. Add references Mention the number of blood samples taken and the total volume of blood taken for the study purpose. Methodology regarding patient visit in both groups needs to be mentioned. Assent needs to be obtained from children above 7 yrs of age.

				<ul style="list-style-type: none"> • Mention in the consent form that you are free to withdraw your child's participation at any time without assigning any reasons. • Mention free treatment will be provided as per JIPMER guidelines. • Mention confidentiality will be maintained during publication of results. • Mention records will be stored for 3 years. • Remove the clause on storage of samples.
29	JIP/IEC/2014/8/383	<p>Investigator: Dr. U.V.U. Vamsidhar Reddy, Junior resident, Medicine</p> <p>Guide: Dr. Abdoul Hamide, Professor</p> <p>Co-Guides: Dr. Jyoti Wadhwa, Associate Professor, General Medicine Dr. Siddartha Das, Assistant Professor, Forensic Medicine Dr. Bhawana A Badhe, Professor, HOD, Pathology Dr. R.P. Swaminathan, Senior Professor and Head, Medicine</p>	Clinical and laboratory profile and outcome of patients with rodenticide poisoning	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention all cases coming during a particular time period will be included. • Clarify when consent will be taken in the protocol. • If retrospective data is to be included, please inform the PGRMC. • Mention records will be stored for 3 years. • Mention confidentiality will be maintained during publication of results. • Include signature of investigator in consent form.
30	JIP/IEC/2014/8/384	<p>Investigator: Dr. Mohammed Turab Jawaid, Junior Resident, Medicine</p> <p>Guide: Dr. Deepak Amalnath, Assistant Professor, Medicine</p> <p>Co-Guide: Dr. DKS Subrahmanyam Professor, Medicine</p>	Clinical profile and outcomes following suicidal Hanging	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention consent will be taken from parents / LAR. • Mention the level of risk as "Minimal risk". • Tamil consent forms should be in concordance with English forms.
31	JIP/IEC/2014/8/385	<p>Investigator: Dr. Ravindrachari.M, Junior Resident, Pulmonary Medicine</p> <p>Guide: Dr. S. Vinod Kumar, Professor and Head, Pulmonary Medicine</p> <p>Co-Guides: Dr. R. Manju, Assistant Professor, Pulmonary Medicine Dr. Negi V S, Professor and Head, Clinical Immunology Dr. Rashmi Kumari, Associate Professor, Dermatology & STD</p>	Pulmonary manifestations in systemic sclerosis: Hospital based descriptive study	<p>To be resubmitted with justification for doing HRCT in all systemic sclerosis patients in writing, with supporting literature.</p>

32	JIP/IEC/2014/8/386	<p>Investigator: Dr. Sivaramakrishna Naik D, Junior Resident, Medicine</p> <p>Guide: Dr. M. Vivekanandan, Additional Professor, Medicine</p> <p>Co-Guide: Dr. Prashanth Sankarrao Adole, Assistant Professor, Biochemistry</p>	Warfarin initiation: a randomized trial comparing the efficacy of 5mg and 10mg initiation nomograms	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format. • Mention how the patient will be treated if bleeding occurs. • Mention interim analysis will be done at 6 months. • Mention when stop rule will be applied. • Mention the level of risk as “More than minimal risk”. • Include investigator’s signature in the consent form. • Numbering needs to be in order in consent form – part 1.
33	JIP/IEC/2014/8/387	<p>Investigator: Dr. K. Karthikeyan, Junior Resident, Medicine</p> <p>Guide: Dr. Suryanarayana BS, Associate Professor, Medicine</p>	Glycemic characteristics in patients with type 2 diabetes mellitus measured using continuous glucose monitoring system – an exploratory study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Mention the level of risk as “More than minimal risk”. • Compensation needs to be provided for participation. • Mention participants uniformly in the protocol. • Mention free treatment will be provided as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons. • Mention that records will be preserved for 3 years. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Numbering needs to be in order in consent forms. • English and Tamil consent forms needs to be in concordance.
34	JIP/IEC/2014/8/388	<p>Investigator: Dr. Shrivarthan.R, Junior Resident, Medicine</p> <p>Guide: Dr. R. P. Swaminathan, Senior Professor and Head, Medicine</p> <p>Co-Guide: Dr. J. Balachander, Medical Superintendent</p>	Clinical and laboratory profile of patients with Isolated Interventricular Septal Hypertrophy	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Mention the level of risk as “Minimal risk”. • Include signature of the investigators. • English and Tamil consent forms needs to be in concordance. • Clarify on benefit for the participants. • Methodology needs to be explained clearly. • Clarify on compensation for participation in the study.
35	JIP/IEC/2014/8/389	<p>Investigator: Dr. Srinath, R, Junior Resident, Medicine</p> <p>Guide: Dr. Jyoti Wadhwa, Associate Professor, Medicine</p> <p>Co-Guides:</p>	Carotid Intima Media thickness , high sensitivity C-reactive protein and Interleukin - 6 in HIV infection and their correlation with immunosuppression	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Remove the clause on storage of samples. • Under methodology, mention how carotid intima media thickness will be measured. • Separate consent forms to be

		Dr. Medha R, Associate Professor, Biochemistry Dr. Sunitha V C ,Assistant Professor, Radiodiagnosis Dr. Abdul Hamide, Professor Medicine		submitted for cases and controls.
36	JIP/IEC/2014/8/390	Investigator: Dr. B Sarath Kumar, Junior Resident, Nuclear Medicine Guide: Dr. Dhanapathi Halanaik, Associate Professor, Nuclear Medicine Co-Guides: Dr. Madhur Kumar Srivastava, Assistant Professor, Nuclear Medicine Dr. Sunil Kumar Saxena, Professor & Head, ENT	Diagnostic Utility of ^{99m} Tc Methoxy Isobutyl Isonitrile (MIBI) for Detecting Residual Gland, Local and Distant Metastases in Post-operative Patients with Differentiated Thyroid Carcinoma (DTC).	Approved subject to following corrections: <ul style="list-style-type: none"> Mention regarding investigations in patient information sheet.
37	JIP/IEC/2014/8/391	Investigator: Dr. Rajubabu, Junior Resident, Orthopedics Guide: Dr. Dilip Kumar Patro, Senior Professor, Orthopedics Co-Guides: Dr. Jagdish Menon, Professor & HOD, Orthopedics Dr. Chittoria Ravi Kumar, Professor HOD, Plastic Surgery	Efficacy of intra articular autologous platelet rich plasma on cartilage repair in grade 1 osteoarthritis knee : A Randomized clinical control trial	Guide Absent
38	JIP/IEC/2014/8/392	Investigator: Dr. Altaf Hussain, Junior Resident, Orthopaedics Guide: Dr. Sandeep Kumar Nema, Assistant Professor, Orthopaedics Co-Guide: Dr. Deep Sharma, Associate Professor, Orthopaedics	Comparison of open reduction internal fixation and above elbow cast for isolated fractures of ulnar shaft	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form needs to be resubmitted in JIPMER IEC format Questionnaire and other annexures provided in English needs to be correctly translated into Tamil. Mention clearly regarding randomization in the methodology. Remove the clause on storage of biological samples. Mention compensation will be provided for unforeseeable risk. English and Tamil consent forms needs to be in concordance.
39	JIP/IEC/2014/8/393	Investigator: Dr. Chanchal Kumar Singh, Junior resident, Orthopedics Guide: Dr. Jagdish Menon, Professor & Head, Orthopedics Co-Guide: Dr. Murali Poduval. Additional Professor, Orthopedics	Radiological and functional outcome of unstable inter trochanteric fractures treated with proximal femoral locking plate.	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form needs to be resubmitted in JIPMER IEC format Include investigator's signature in ICF-2. English and Tamil consent forms needs to be in concordance.
40	JIP/IEC/2014/8/394	Investigator: Dr. Ganeswar Barik, Junior Resident, Obstetrics & Gynaecology Guide:	Role of oxidative stress and antioxidants in male infertility-- An interventional study	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form needs to be resubmitted in JIPMER IEC format Mention the study design as interventional study.

		<p>Dr. Latha Chaturvedula, Professor, Obstetrics & Gynaecology</p> <p>Co-Guide: Dr. Zachariah Bobby, Professor and Head, Biochemistry</p>		<ul style="list-style-type: none"> • Mention participant can withdraw from the study without assigning any reasons. • Mention that records will be preserved for 3 years. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Include participant's signature in consent form part II. • In the case record form only patient code needs to be entered. Name and patient code needs to be maintained in a separate confidential register. • English and Tamil consent forms needs to be in concordance.
41	JIP/IEC/2014/8/395	<p>Investigator: Dr. R Nithya, Junior resident, Obstetrics & Gynaecology</p> <p>Guide: Dr. Kubera NS, Associate Professor, Obstetrics & Gynaecology</p> <p>Co-Guide: Dr. Nivedita Mondal, Assistant Professor, Pediatrics</p>	Maternal and Perinatal outcome among Women with and without Infertility- A cross sectional study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Include signature of witness and participant in ICF-2 • Mention participant can withdraw from the study without assigning any reasons. • Mention compensation will be provided for unforeseeable risk as per JIPMER guidelines. • Mention that records will be preserved for 3 years. • English and Tamil consent forms needs to be in concordance. • Delete phrase on storage of samples in ICF-2
42	JIP/IEC/2014/8/396	<p>Investigator: Dr. Nafeez Shaik, Junior Resident, Obstetrics and Gynaecology</p> <p>Guide: Dr. Manikandan K, Associate Professor, Obstetrics and Gynaecology</p> <p>Co-Guides: Dr. Anish Keepanasseril, Assistant Professor, Obstetrics and Gynaecology Dr. Adhisivam.B, Associate Professor, Paediatrics</p>	Longitudinal changes in Doppler parameters in intrauterine growth restricted fetuses and their correlation with perinatal outcome: a prospective cohort study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Mention only pregnant women above > 18 yrs will be included. • Mention that records will be preserved for 3 years. • Mention compensation will be provided for unforeseeable risk as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • English and Tamil consent forms needs to be in concordance. • Delete phrase on storage of samples in ICF-2
43	JIP/IEC/2014/8/397	<p>Investigator: Dr. Ontela Vijaya, Junior Resident,</p>	Effect of antenatal corticosteroids on respiratory morbidity in	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format

		Obstetrics&Gynaecology Guide: Dr. Gowri Dorairajan, Professor,Obstetrics &Gynaecology	late preterm newborns- a randomized controlled trial	<ul style="list-style-type: none"> • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for unforeseeable risk as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • English and Tamil consent forms needs to be in concordance. • Remove the clause on storage of biological samples in ICF-2. • Mention interim analysis will be done to decide upon continuation of the study depending on the results.
44	JIP/IEC/2014/8/398	Investigator: Dr. Nithya. R, Junior Resident, Obstetrics & Gynaecology Guide: Dr. Dasari Papa, Professor, Obstetrics & Gynaecology	Comparison of Metformin and Insulin for the treatment of Gestational Diabetes Mellitus – A Randomised Controlled Trial	Approved subject to following corrections: <ul style="list-style-type: none"> • DCGI approval is obtained. • Consent form needs to be resubmitted in JIPMER IEC format • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • Mention that records will be preserved for 3 years. • English and Tamil consent forms needs to be in concordance. • Mention free treatment will be provided if lactic acidosis occurs.
45	JIP/IEC/2014/8/399	Investigator: Dr. E. Priyanka Devi, Junior Resident, Obstetrics and Gynaecology Guide: Dr. Sasirekha R, Associate Professor, Obstetrics and Gynaecology Co-Guides: Dr. Latha Chaturvedula, Professor, Obstetrics and Gynaecology Dr. Jayanthi M, Associate Professor, Pharmacology	Effect of tranexamic acid on blood loss at elective caesarean section: a double blind randomized controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention the level of risk as More than minimal risk. • DCGI approval should be obtained. • Consent form needs to be submitted as per JIPMER IEC format. • Mention only participants > 18 yrs will be included in the study. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines.

				<ul style="list-style-type: none"> • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • Mention that records will be preserved for 3 years. • English and Tamil consent forms needs to be in concordance. • Avoid using non medical jargons in the consent forms.
46	JIP/IEC/2014/8/400	<p>Investigator: Dr. Jerene Mathews, Junior Resident, Skin & STD,</p> <p>Guide: Dr. Laxmisha C, Associate Professor, Skin & STD</p> <p>Co-Guides: Dr. Devinder Mohan Thappa, Professor, Skin & STD Dr. Rajesh N G, Associate Professor, Pathology</p>	Merkel cell density and touch-domes in vitiligo	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • English and Tamil consent forms needs to be in concordance regarding storage of records.
47	JIP/IEC/2014/8/401	<p>Investigator: Dr. Gadipudi Avanthi, Junior Resident, Obstetrics & Gynaecology</p> <p>Guide: Dr. Haritha Sagili, Associate Professor, Obstetrics & Gynaecology</p> <p>Co-Guides: Dr. Dasari Papa, Professor, Obstetrics & Gynaecology</p>	Tamoxifen for Ovulation Induction in Infertile Women with Polycystic Ovarian Syndrome who did not conceive with Three Cycles of Clomiphene Citrate - A Prospective Clinical Study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • DCGI approval is obtained. • Consent form needs to be resubmitted in JIPMER IEC format • Mention regarding provision of compensation if foreseeable and unforeseeable risk occurs. • Clarify on duration storage of records. • Mention the level of risk as “More than minimal risk”.
48	JIP/IEC/2014/8/402	<p>Investigator: Dr. Sindhura Vaddamani, Junior Resident, Obstetrics & Gynecology</p> <p>Guide: Dr. Anish Keepanasseril, Associate Professor, Obstetrics & Gynecology</p> <p>Co-Guides: Dr. Ajith Anantha Pillai, Associate Professor, Cardiology Dr. Manikandan K, Associate Professor, Obstetrics & Gynecology</p>	Comparison of Maternal Cardiovascular function in women with Early Onset Preeclampsia and Late Onset Preeclampsia – A Cross Sectional Study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • Mention that records will be preserved for 3 years. • English and Tamil consent forms needs to be in concordance.
49	JIP/IEC/2014/8/403	<p>Investigator: Dr. Nandhini. B, Junior Resident, Obstetrics & Gynaecology</p> <p>Guide: Dr. Dilip Kumar Maurya, Associate Professor, Obstetrics & Gynaecology</p> <p>Co-Guide: Dr. Anish Keepanasseril, Associate Professor, Obstetrics</p>	Efficacy of vaginal Misoprostol in cervical priming in women undergoing vaginoscopic hysteroscopy : A Randomised Controlled Trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Mention level of risk as more than minimal risk • Clarify regarding direct benefit to the participants. • Mention the total duration of study participation. • Mention that records will be preserved for 3 years.

		& Gynaecology		<ul style="list-style-type: none"> • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • English and Tamil consent forms needs to be in concordance. • Explain methodology in simple language.
50	JIP/IEC/2014/8/404	<p>Investigator: Dr. Naidu Archana, Junior Resident, Obstetrics & Gynaecology</p> <p>Guide: Dr. T. Chitra, Assistant Professor, Obstetrics & Gynaecology</p> <p>Co-Guide: Dr. Latha Chaturvedula, Professor, Obstetrics & Gynaecology</p>	Comparing low dose human menopausal gonadotrophins with clomiphene citrate for ovarian stimulation in intrauterine insemination-a randomized controlled trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format • Mention level of risk as more than minimal risk • Clarify regarding direct benefit to the participants. • Clarify on compensation to the participants. • Tamil consent form needs to be resubmitted with simple language. • Clarify on storage of biological samples. • Mention regarding sample size and randomization procedure completely under methodology. • Mention that records will be preserved for 3 years. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • English and Tamil consent forms needs to be in concordance.
51	JIP/IEC/2014/8/405	<p>Investigator: Dr. S. Manikandan, Junior Resident, Preventive and Social Medicine</p> <p>Guide: Dr. K.C. Premarajan, Professor, Preventive and Social Medicine</p> <p>Co-Guides: Dr. Ganesh Kumar S, Associate Professor, Preventive and Social Medicine Dr. Vikas Menon, Asst.</p>	Study of prevalence of stress among higher secondary school children in urban area of Puducherry	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent needs to be obtained from the parents directly by the investigator. • Separate assent form needs to be submitted for children > 7 years of age. • Mention that records will be preserved for 3 years. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • English and Tamil consent forms needs to be in concordance.

		Professor, Psychiatry		<ul style="list-style-type: none"> • Clarify on storage of data. • Questionnaires regarding smoking and drinking behaviour of Father needs to be removed or mention in inclusion criteria only students whose father has smoking and drinking habits will be included. • Mention confidentiality will be maintained while analysis, presentation and publication of results.
52	JIP/IEC/2014/8/406	Investigator: Dr. Aswathy Viswanathan, Junior resident, Physiology Guide: Dr. Velkumary, Associate Professor, Physiology Co-Guide: Dr. G. K. Pal, Prof & Head, Physiology	Effect of 12 weeks practice of chandranadi pranayama on cardiac autonomic functions and biochemical parameters in young male prehypertensive adults: a randomized controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Include screening proforma in the study protocol. • If participants are recruited through advertisement, advertisement form needs to be submitted to IEC for approval. • When staff volunteers are recruited for the study, those from the department of Physiology should not participate in the study. This should be mentioned clearly in the Methodology. • Include life style modifications in both groups. • Expected duration of study needs to be changed to 12 wks. • Mention how many times and how much blood sample will be collected under methodology. • Mention that records will be preserved for 3 years. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care. • Clarify regarding storage of samples. • Numbering of references needs to be corrected.
53	JIP/IEC/2014/8/407	Investigator: Dr. K. Keni Gowsi, Junior Resident, Physiology Guide: Dr. Vivek Kumar Sharma, Additional Professor, Physiology Co-Guide: Dr. G. K. Pal, Professor and Head , Assistant Professor, Physiology	Comparison of cognition, inflammation and insulin resistance at baseline and after acute bouts of moderate intensity and high intensity exercise in male athletes and non-athletes - a randomized control trial	Candidate Absent
54	JIP/IEC/2014/8/408	Investigator: Dr. Subathra T. A, Junior Resident, Physiology Guide:	Association of sympathovagal imbalance, insulin resistance and oxidative	Approved subject to following corrections: <ul style="list-style-type: none"> • Please simplify the language in the consent forms. • Include cognitive deficit assessment in

		<p>Dr. G. K. Pal, Professor & Head, Physiology</p> <p>Co-Guides: Dr. R. P. Swaminathan, Professor & Head, Medicine Dr. Y. Dhanalakshmi, Assistant Professor, Physiology</p>	<p>stress with cognitive deficit in patients with newly diagnosed prehypertension and hypertension</p>	<p>the objective</p> <ul style="list-style-type: none"> • Mention in the methodology in both the protocol and the consent forms how cognitive deficit will be assessed. • Mention breakfast will be given for participants. • Mention compensation will be provided for participation in the study. • Mention the level of risk as Minimal risk. • Remove the clause on storage of samples. • English and Tamil consent forms need to be in concordance. • Mention that records will be preserved for 3 years. • Mention confidentiality will be maintained while analysis, presentation and publication of results. • Mention benefit to the participants if cognitive deficit is detected. • Mention participant can withdraw from the study without assigning any reasons and this will not affect their medical care.
55	JIP/IEC/2014/8/409	<p>Investigator: Dr. Nishanthi.A, Junior Resident, Pharmacology</p> <p>Guide: Dr. Steven. A. Dkhar, Professor, Pharmacology</p> <p>Co-Guides: Dr. Sandhiya. S, Assistant Professor, Clinical Pharmacology Dr. Zachariah Bobby, Professor and Head, Biochemistry Dr. Kadhiraavan. T, Associate Professor, Medicine Dr. Sadish Kumar Kamalanathan, Associate Professor, Endocrinology</p>	<p>Effect of Vitamin D Supplementation on Vascular Functions in Type 2 Diabetic Patients with Vitamin D Deficiency</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention that records will be preserved for 3 years for further analysis and follow-up. • Mention compensation will be provided for foreseeable and unforeseeable risks given as per JIPMER rules and delete the phrase “depending upon the nature of the injury”.
56	JIP/IEC/2014/8/410	<p>Investigator: Dr. Porkodi. A, Junior Resident, Pharmacology</p> <p>Guide: Dr. D.G. Shewade, Professor, Pharmacology</p> <p>Co-Guides: Dr. A. Surendiran, Assistant Professor, Pharmacology Dr. K. Gunaseelan, Associate Professor, Radiotherapy</p>	<p>Influence of ABCB1 genetic polymorphisms on the antiemetic response to ondansetron based medication for cisplatin based chemotherapy in South Indian cancer patients visiting Regional Cancer Centre, JIPMER.</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention under methodology that participant will be contacted over telephone, only if they give consent to be called over telephone. • In ICF-2, include a phrase that the participant agrees to be contacted by phone/directly during the course of the study for follow-up. • Include choice of the patient regarding storage of biological samples.
57	JIP/IEC/2014/8/411	<p>Investigator: Dr. Saranya Mohan, Junior Resident of Pathology</p> <p>Guide: Dr. N. Siddaraju, Professor,</p>	<p>Immunocytochemical Evaluation of Malignant Serous Effusions to Establish the Primary Site of Malignancy</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Anonymization of data needs to be followed to maintain confidentiality. • Waiver of consent granted.

		Pathology Co-Guides: Dr. Pampa Ch Toi, Associate Professor, Pathology Dr. Biswajit Dubashi, Professor and Head, Medical Oncology		
58	JIP/IEC/2014/8/412	Investigator: Dr. Pavithra. A, Junior Resident, Pathology Guide: Dr. Debdatta Basu, Professor, Pathology Co-Guides: Dr. Rakhee Kar, Associate Professor, Pathology Dr. Biswajit Dubashi, Associate Professor, Medical Oncology	Post chemotherapy changes in bone marrow in acute leukemia with emphasis on detection of residual disease by immunohistochemistry	Approved subject to following corrections: <ul style="list-style-type: none"> • Explain the methodology clearly. • Can ask for waiver of consent, subject to anonymization of data to maintain confidentiality.
59	JIP/IEC/2014/8/413	Investigator: Dr. Chikhale Mangesh Vilasrao, Junior Resident, Pathology Guide: Dr. Pampa Ch. Toi, Associate Professor, Pathology Co-Guide: Dr. N. Siddaraju, Professor, Pathology Dr. A. Ramesh, Associate Professor, Radiodiagnosis	Efficacy of an immunopanel of arginase-1, glypican-3, heppar-1, ttf-1 and ck-19 in distinguishing hepatocellular carcinoma from its mimics on fine needle aspiration cytology	Approved subject to following corrections: <ul style="list-style-type: none"> • Explain the methodology clearly. • Can ask for waiver of consent, subject to anonymization of data to maintain confidentiality.
60	JIP/IEC/2014/8/414	Investigator: Dr. Vidya, Junior Resident, Paediatrics Guide: Dr. Sriram Krishnamurthy, Associate Professor, Paediatrics Co-Guides: Dr. Renitha Raghavan, Assistant Professor, Pediatrics. Dr. Medha R., Associate Professor, Biochemistry	Evaluation of non-autoimmune subclinical and overt hypothyroidism in steroid resistant nephrotic syndrome	Approved subject to following corrections: <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format. • Contact number of investigator should be included in the consent forms • Change the level of risk as “Minimal risk”. • Mention how many blood samples and blood volume will be collected under methodology. • Mention the expected duration of the participant clearly. • Mention only children < 18 yrs of age will be included. • Clarify on storage of biological samples. • Mention compensation for foreseeable and unforeseeable risks given as per JIPMER rules.
61	JIP/IEC/2014/8/415	Investigator: Dr. Shavani, Junior Resident, Pediatrics Guide: Dr. Sriram Krishnamurthy, Associate Professor, Paediatrics Co-Guides:	Comparison of two vitamin D dosing regiments for osteoprotection in children with new-onset and infrequently relapsing nephrotic treated with steroids : a randomized controlled	Approved subject to following corrections: <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format. • Contact number of investigator should be included in the consent forms • Methodology needs to be written clearly. • Tamil consent forms needs to be in

		Dr. Sadish Kumar, Associate Professor, Endocrinology Dr. Medha R., Associate Professor, Biochemistry	trial	<p>concordance with English consent form.</p> <ul style="list-style-type: none"> • Study can be mentioned as a randomized trial as there is no control group. • Mention the expected duration of participation in both groups.
62	JIP/IEC/2014/8/416	<p>Investigator: Dr. Ch. Pavani, Junior Resident, Paediatrics</p> <p>Guide: Dr. C. Venkatesh, Assistant Professor, Paediatrics</p> <p>Co-Guide: Dr. Soundaravalli, Associate Professor, Biochemistry</p>	Serum ionised magnesium level in children with mild persistent asthma and its correlation with symptom control	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Change the level of risk as “Minimal risk”. • Mention the expected duration of participation. • Consent form needs to be resubmitted in JIPMER IEC format.
63	JIP/IEC/2014/8/417	<p>Investigator: Dr. Gayathri Bhuvaneshwaran Kartha, Junior Resident, Pediatrics</p> <p>Guide: Dr. Ramesh Kumar R, Assistant Professor, Pediatric Critical Care Units</p> <p>Co-Guide: Dr. S. Mahadevan, Senior Professor of Pediatrics and Dean, Pediatric Critical Care Units</p>	Ringer’s lactate versus normal saline for children with severe dehydration due to acute diarrhea: A randomized double blind controlled trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Written clarification needs to be provided for queries on DCGI approval and waiver of consent.
64	JIP/IEC/2014/8/418	<p>Investigator: Dr. Gopinathan M, Junior Resident, Paediatrics</p> <p>Guide: Dr. Barath J, Assistant Professor, Paediatrics</p>	Factors affecting age at admission of infants with cholestasis in JIPMER- a descriptive study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format. • Methodology needs to be explained clearly. • Clarify regarding compensation for study related injury. • Consent forms should be for parents/LAR. • Assent form needs to be removed. • Tamil consent forms needs to be in concordance with English consent form.
65	JIP/IEC/2014/8/419	<p>Investigator: Dr. Dhayaguruvasan. M, Junior Resident, Pediatrics</p> <p>Guide: Dr. Vishnu Bhat, Senior Professor and Head, Pediatrics</p> <p>Co-Guide: Dr. Harish, Senior Professor and Head, Microbiology</p>	Effect of Chlorhexidine Treated Baby Sheets on the Incidence of Neonatal Sepsis –A Randomised Controlled Trial	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent form needs to be resubmitted in JIPMER IEC format. • Tamil consent forms needs to be in concordance with English consent form. • Mention compensation will be provided for foreseeable and unforeseeable risks given as per JIPMER rules. • Consent form language has to be changed as it for parents/LAR. • Mention the level of risk as “Minimal risk”.
66	JIP/IEC/2014/8/420	<p>Investigator: Dr. Lakshmi Madhumathi.M,</p>	Febrile Neutropenia in Children: Clinical	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Include assent form for children

		Junior Resident, Pediatrics Guide: Dr. Niranjan Biswal, Professor, Pediatrics	Profile and Outcome	above 7 years. <ul style="list-style-type: none"> Mention under outcome “afebrile for 48 hrs instead of 24 hrs”.
67	JIP/IEC/2014/8/421	Investigator: Dr. Dulasi Durga K, Junior Resident, Paediatrics Guide: Dr. Adhisivam B, Associate Professor, Paediatrics Co-Guide: Dr. Vishnu Bhat B, Professor & Head, Paediatrics	Oxidative stress and DNA damage in newborns born to mothers with hyperglycemia.	Approved subject to following corrections: <ul style="list-style-type: none"> Remove the clause on storage of biological samples. Mention the procedure of cord blood collection as per ICMR guidelines for biomedical research in human participants (2006). Clarify on informing the findings to the participant.
68	JIP/IEC/2014/8/422	Investigator: Dr. Singanamalla Bhanudeep, Junior Resident, Pediatrics Guide: Dr. S. Mahadevan, Dean and Division Head – Pediatric Critical Care Unit Co-Guide: Dr. Ramesh Kumar R, Assistant Professor, Pediatric Critical Care Units	Practice audit of red blood cell transfusion in critically ill children admitted in pediatric intensive care unit in JIPMER-A prospective observational study	To be resubmitted with change of methodology: <ul style="list-style-type: none"> Level of risk to be changed as minimal risk Suggested to ask for waiver of consent.
69	JIP/IEC/2014/8/423	Investigator: Dr. Karamalla Saddam Hussain, Junior, Resident, Paediatrics Guide: Dr. Reena Gulati, Associate Professor, Paediatrics Co-Guides: Dr. Santhosh Satheesh, Associate Professor and Head, Cardiology Dr. V.S. Negi, Professor and Head, Clinical Immunology	Cardiovascular risk in children with Juvenile Idiopathic Arthritis- a comparative study	Guide absent.
70	JIP/IEC/2014/8/424	Investigator: Dr. Kirankumar.M, Junior Resident, Pediatrics Guide: Dr. Niranjan Biswal, Professor, Pediatrics Co-Guides: Dr. P.Narayanan, Associate Professor, Pediatrics Dr. Nivedita Nanda, Assistant Professor, Pediatrics	Vitamin D,25(OH)D Status at admission and its association with Mortality Children admitted to PICU	To be resubmitted with change of methodology: <ul style="list-style-type: none"> Consent form needs to be resubmitted in JIPMER IEC format. Retrospective grouping of cases being done as per vitamin D status, hence the proposal needs to be resubmitted with change in the methodology accordingly, as discussed. Mention level of risk as ‘Minimal risk’. Clarify on storage of biological samples. Mention compensation will be provided for foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines. Tamil consent form needs to be in concordance with English consent forms.
71	JIP/IEC/2014/8/425	Investigator:	Neurodevelopmental	Approved subject to following corrections:

		Dr. Laxman Singh .D, Junior Resident, Paediatrics Guide: Dr. Vishnu Bhat B, Professor & HOD, Paediatrics Co-Guide: Dr. Nishad Plakkal, Assistant Professor, Pediatrics	outcome of very low birth weight (VLBW) neonates with culture-positive blood stream infection – PROSPECTIVE CASE CONTROL STUDY	<ul style="list-style-type: none"> Consent form needs to be resubmitted in JIPMER IEC format. Clarify regarding level of risk Mention in the protocol which chart will be used to assess neurodevelopmental outcome and provide copy of the chart as an annexure to the IEC (in English and Tamil). Consent form language has to be changed as it for parents/LAR Remove the clause on storage of biological samples.
72	JIP/IEC/2014/8/426	Investigator: Dr. Anitha. A, Junior Resident, Pediatrics Guide: Dr. S. Mahadevan, Senior Professor of Pediatrics and Dean, Division Head Pediatric Critical Care Units Co-Guide: Dr. Ramesh Kumar R, Assistant Professor, Pediatric Critical Care Units	A pilot study on the second dose of scorpion antivenom in children with non resolving scorpion sting envenomation	To be resubmitted with addition of the relevant references for using second dose of scorpion sting anti venom in children.
73	JIP/IEC/2014/8/427	Investigator: Dr. Reshmi Raveendran, Junior Resident, Paediatrics Guide: Dr. Adhisivam .B, Associate Professor, Paediatrics Co-Guide: Dr. Nivedita Mondal, Assistant Professor, Paediatrics	Perinatal risk stratification of preterm neonates and developmental outcome, a prospective study	Absent
74	JIP/IEC/2014/8/428	Investigator: Dr. Sohini Chattopadhyay, Junior Resident, Paediatrics Guide: Dr. Narayanan P, Associate Professor, Paediatrics	Evaluation of central venous partial pressure of oxygen and its association with central venous saturation of oxygen among children admitted in paediatric intensive care unit with septic shock	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form needs to be modified in JIPMER IEC format. Remove the clause on storage of samples. Please write the consent forms in simple language.
75	JIP/IEC/2014/8/429	Investigator: Dr. V. Muthukrishnan , Junior Resident, Psychiatry Guide: Dr. Raviphilip Rajkumar, Associate Professor, Psychiatry Co-Guide: Dr. Balaji Bharadwaj, Assistant Professor, Psychiatry	A comparative study of psychotic symptoms and their correlates in patients with three major psychoses - schizophrenia, bipolar affective disorder and acute transient psychotic disorder	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form from caregiver/LAR needs to be submitted Mention the exact expected duration of participation. Consent form needs to be modified in JIPMER IEC format and needs to be in simple language.
76	JIP/IEC/2014/8/430	Investigator: Dr. P. Venkatalakshmi, Junior Resident, Psychiatry Guide: Dr. Shivanand Kattimani, Associate Professor, Psychiatry Co-Guides:	Assessing serum Brain Derived Neurotrophic Factor and Matrix Metalloproteinase -9 levels and their correlation with Cognitive Function in	Approved subject to following corrections: <ul style="list-style-type: none"> Consent form from caregiver/LAR needs to be submitted Mention the exact expected duration of participation. Consent form needs to be modified in JIPMER IEC format and needs to be

		Dr. Nandeesh H, Assistant Professor, Biochemistry Mr. Arivazhagan K, Tutor cum Clinical Psychologist, Psychiatry	Bipolar I disorder in remission	<p>in simple language.</p> <ul style="list-style-type: none"> Clarify regarding storage of biological samples.
77	JIP/IEC/2014/8/431	<p>Investigator: Dr. Shiva Kumar Siripuram, Junior Resident, Radiotherapy</p> <p>Guide: Dr. Parthasarathy, Additional Professor, Radiotherapy</p> <p>Co-Guide: Dr. ShyamaPrem S, Associate Professor, Radiotherapy</p>	The Effect Of Combined Intracavitary-Interstitial Brachytherapy For Carcinoma Cervix Involving Lower 1/3rd Of Vagina: A Descriptive Study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention the level of risk as “Minimal risk”. Interim analysis needs to be presented in IEC after completion of 20 participants, for seeking further approval for continuation of the study. Provide references for the regimen used in this study.
78	JIP/IEC/2014/8/432	<p>Investigator: Dr. Mrutyunjayaroo Muvvala, Junior Resident, Radiotherapy</p> <p>Guide: Dr. K. Gunaseelan, Associate Professor, Radiotherapy</p> <p>Co-Guides: Dr. Kadambari.D, Professor, General Surgery Dr. Vijaya Prabhu.N, Lecturer, Radiotherapy</p>	Localization of tumor bed for boost radiation following breast conservation surgery. A descriptive study	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Explain the methodology clearly and clearly mention about the virtual plan. Consent forms to be resubmitted in the JIPMER IEC format. Rewrite the consent forms in simple language and mention that there is no intervention involved.
79		<p>Investigator: Dr. Ambedkar Yadala, Junior Resident, Radiotherapy</p> <p>Guide: Dr. Ashutosh Mukherji, Associate Professor, Radiotherapy</p> <p>Co-Guides: Dr. Biswajit Dubashi, Associate Professor, Medical Oncology Dr. N Vijayaprabhu, Lecturer, Medical Physics Dr. Vikas Menon, Assistant Professor, Psychiatry Dr. Deepak Bharathi, Assistant Professor, Radiodiagnosis</p>	To assess the cognitive and dosimetric analysis in patients of acute lymphoblastic leukemia (ALL) receiving Prophylactic cranial irradiation (PCI) through volumetric arc radiotherapy by hippocampal sparing	<p>To be resubmitted with following corrections:</p> <ul style="list-style-type: none"> Consent forms to be resubmitted in the JIPMER IEC format. Include assent form for children above 7 years in addition to consent form for parent / LAR. Consent form for participants above 18 years of age has to be included. Mention relapse is more with hippocampal sparing in the patient information sheet. In the protocol, delete the phrase duration of the study “from October 2014 to July 2016”.
80	JIP/IEC/2014/8/433	<p>Investigator: Dr. Prema. S, Junior Resident, Radio-Diagnosis</p> <p>Guide: Dr. Deepak Barathis, Assistant Professor, Radio-Diagnosis</p> <p>Co-Guides: Dr. Jayalakshmi. d, Additional Professor, Obstetrics and Gynaecology Dr. Ramesh Babu, K, Associate Professor, Ophthalmology</p>	Ophthalmic artery doppler profile and its correlation with severity in pre-eclampsia	Approved
81	JIP/IEC/2014/8/434	<p>Investigator: Dr. Mohsina Subair, Junior</p>	Comparison of Adapted Enhanced Recovery	Approved

		Resident, Surgery Guide: Dr. Vikram Kate, Professor, Surgery Co-Guide: Dr. Shanmugam D, Assistant Professor, Surgery	After Surgery Pathway versus Standard Care following Simple Closure of Perforated Duodenal Ulcer-A Randomised Controlled Trial	
82	JIP/IEC/2014/8/435	Investigator: Dr. Jubel J Kunnathoor, Junior Resident, General Surgery Guide: Dr. S. Suresh Kumar, Assistant Professor, Surgery Co-Guide: Dr. Manwar Ali. S, Associate Professor, Surgery	Comparing Surgical Site Infection and Scar Cosmesis between Conventional Linear Skin Closure Vs. Purse String Skin Closure in Stoma reversal - A Randomized Controlled Trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Mention the level of risk as “Minimal risk”. • Change expected duration of participation as 3 months. • Remove the clause on storage of biological samples.
83	JIP/IEC/2014/8/436	Investigator: Dr. Manoj Kumar Patta, Junior Resident, General Surgery Guide: Dr. K. Srinivasan, Professor and HOD, General Surgery Co-Guide: Dr. V. Gomathi Shankar, Assistant Professor, General Surgery	Role of iodine impregnated adhesive drapes in prevention of surgical site infection following elective inguinal hernia repair.	Approved subject to following corrections: <ul style="list-style-type: none"> • English and Tamil consent forms need to be in concordance.
84	JIP/IEC/2014/8/437	Investigator: Dr. Ranjith Kumaran K S. M, Junior Resident, General Surgery Guide: Dr. Sarath Chandra Sistla, Professor, General Surgery Co-Guides: Dr. Balamourougan K, Assistant Professor, Surgery Dr. Pankaj Kundra, Professor and Head, Anaesthesiology and Critical Care	Effect of transversus abdominis plane block on post operative pain relief following inguinal hernia repair under local anaesthesia: a randomized controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Mention the level of risk as “Minimal Risk”. • Clarify the clause on DCGI approval.
85	JIP/IEC/2014/8/438	Investigator: Dr. Rajnish Kumar, Junior Resident, Surgery Guide: Dr. S. Manwar Ali, Associate Professor, Surgery Co-Guide: Dr. S. Suresh Kumar, Assistant Professor, Surgery	Comparison between conventional and cliplless laparoscopic cholecystectomy: A randomised controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Mention the level of risk as “Minimal risk”. • Expected duration of participation needs to be mentioned.
86	JIP/IEC/2014/8/439	Investigator: Dr. K. Sree Harsha, Junior Resident, Surgery Guide: Dr. Vishnu Prasad. N.R, Professor, Surgery Co-Guide: Dr. A. Anandhi, Assistant Professor, Surgery	Short term outcomes following laparoscopic repair of para-umbilical hernia	Approved
87	JIP/IEC/2014/8/440	Investigator:	Intra-operative	Approved

		Dr. Murali Krishna Padyala, Junior Resident, General Surgery Guide: Dr. D. Kadambari, Professor, General Surgery Co-Guides: Dr. Shanmugam, Assistant Professor, General Surgery Dr. Sunil Kumar Saxena, Professor & Head, ENT	identification of parathyroid glands and recurrent laryngeal nerves during thyroid surgery using methylene blue. a randomised controlled trial	
88	JIP/IEC/2014/8/441	Investigator: Dr. Ananthkumar. S, Junior Resident, General Surgery Guide: Dr. Kadambari. D, Professor, General Surgery	Comparison of the efficacy of Oral Tamoxifen with Topical Analgesics on pain among patients with mastalgia- A randomized clinical trial	Approved subject to following corrections: <ul style="list-style-type: none"> • DCGI approval needs to be obtained before commencing the study. • Change the level of risk as “More than minimal risk”.
89	JIP/IEC/2014/8/442	Investigator: Dr. C. Adithan, Senior Professor & Head, Clinical Pharmacology Co- Principal Investigator: Dr. S. Sandhiya, Assistant Professor, Clinical Pharmacology Co-Investigators Dr. RP Swaminathan, Senior Professor & Head, Medicine Dr. Santhosh Satheesh, Additional Professor & Head, Cardiology Dr. BV Sai Chandran, Additional Professor & Head, Cardio Thoracic & Vascular Surgery	Efficacy and safety of conventional vs genomic algorithm guided warfarin dosing in South Indians – a randomized double blind controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • Level of risk to be corrected as more than minimal risk
90	JIP/IEC/2014/8/443	Investigator: Dr. Ramesh Kumar R, Assistant Professor, Paediatrics Co-Investigator: S. Mahadevan, Dean and Division Head –Pediatric Critical Care Unit, Paediatrics	Dexmedetomidine versus midazolam for sedation in mechanically ventilated children in pediatric intensive care unit: A randomized, double-blind controlled trial	Approved subject to following corrections: <ul style="list-style-type: none"> • DCGI approval needs to be obtained before commencing the study.
91	JIP/IEC/2014/8/444	Investigator: Dr. Chitra Rajeswari T, Assistant professor, Anesthesiology Co-Investigator: Dr. Aswini. N, Senior resident, Anesthesiology Dr. Veena. P, Associate professor, Obstetrics and Gynaecology	Influence of Anesthetic Technique on Maternal and Fetal outcome in Category 1 Cesarean Section: An Observational study	Approved subject to following corrections: <ul style="list-style-type: none"> • Request for waiver of consent rejected. • Consent needs to be obtained from all the study participants.
92		Investigator: Dr. Gopala Krishnan, Associate Professor, Neuro Surgery, JIPMER.	Randomised controlled trial of the efficacy of ampicillin versus ceftriaxone for prevention of meningitis in traumatic	<ul style="list-style-type: none"> • The study can be continued. • Stopping rule has to be mentioned and resubmitted to the IEC. • The SAE will be reviewed by the competent authority and opinion will

			pneumocephalus	be given to the IEC for further review,
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IEC- Institute Ethics Committee, LAR-Legally acceptable representative, DCGI-Drug Controller of India

(Dr. T.K. Dutta)
Member-Secretary,
Institute Ethics Committee (Human Studies)

Mr. E.V. Kumar
Chairman,
Institute Ethics Committee (Human Studies)

To

A) INSTITUTE ETHICS COMMITTEE MEMBERS

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13.	Ms. Usha, Puducherry	Member
14.	Mrs. M. Vasuki, Puducherry	Member

B) Administrator, JIPMER website

Copy to PS to Director, Medical Superintendent, Dean (Research) for information.