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JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION AND RESEARCH
(Institution of National Importance under Ministry of Health & Family Welfare, Government of India)
Dhanvantari Nagar, PUDUCHERRY - 605 006

No.DCP/IEC-1/2014

Date: 05.02.2014

Minutes of First Meeting of the Institute Ethics Committee (Human Studies) for the year 2014 held on 29.01.2014 & 30.01.2014

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The first meeting of the Institute Ethics Committee (Human Studies) for the year 2014 was held on Board Room No.316, III Floor of the Administrative Block, JIPMER, on 29.01.2014 (Wednesday) & 30.01.2014 (Thursday) at 9.30 AM under the Chairmanship of Shri.S.Nadamuni, District Judge (Retd). On 29.01.2014, the meeting was attended by the Chairman, Dr. Zile Singh (Member), Dr. Vasantha Muthuswamy (Member), Dr.Santosh Kumar (Member), Dr. K. Chandrasekaran (Member), Dr. N. Sakthivel (member), Dr. M.G. Sridhar (Member), Ms.Usha (Member), Mrs. M. Vasuki (Member) and Dr. C. Adithan (Member Secretary). On 30.01.14 the meeting was attended by the Chairman, Dr. A.K. Das (Member), Dr. Zile Singh (Member), Dr. Santosh Kumar (Member), Dr. K. Chandrasekaran (Member), Dr. N. Sakthivel (member), Dr. M.G. Sridhar (Member), Ms.Usha (Member), Mrs. M. Vasuki (Member) and Dr. C. Adithan (Member Secretary), besides the concerned faculty and the post graduate students.

The agenda of the meeting was as follows:

1. Approval of minutes of previous Institute Ethics Committee Meeting held on 25.11.2013
2. Approval of Minutes of Sub Committee Meeting held on 17.01.2014
3. New research proposals – 65 Nos
4. Proposals forwarded by Institute Ethics Sub Committee – 12 Nos
5. Any other items with permission of Chairman

The meeting started at 9.30 am with a welcome address by Member Secretary. The Chairman emphasized the importance of keeping the study participants comfortable and safe in the clinical study. He also mentioned that informed consent should be obtained after giving complete information to the participants.

Video recording of informed consent:

The Member Secretary circulated the DCGI order dated 19-11-13, which mentions that **"audio- visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his / her understanding on such consents is required to be done while adhering to the principles of confidentiality. Such audio visual recording and related documentation would be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including global clinical trials."** He

requested the members to give their opinion whether this will be applicable to clinical trials of already marketed drugs done by JIPMER faculty and research scholars. Dr. Vasantha Muthusamy (Former Senior DDG, ICMR) clarified that **“audio- visual recording of the informed consent process” is essential only for new drug trials coming under schedule Y** and if study is on vulnerable population. She also mentioned that audiovisual (AV) recording is for the entire IC process and the video should be kept confidential and should be released only for legal requirements. **She also mentioned that there is no requirement for AV consent for trials done using marketed drugs for approved indication.** Further it was noted that as per schedule Y, Rule 122-DAA, clinical trial is defined as **“for the purpose of this part “clinical trial” means a systematic study of new drug(s) in human subject(s) to generate data for discovering and / or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) and / or adverse effects with the objective of determining safety and / or efficacy of the new drug”.** Therefore it was decided that audio-visual recording of informed consent process is to be strictly followed for all clinical trial coming under schedule Y, Rule 122-DAA.

The minutes of the subcommittee meeting held on 25-11-13 were distributed to the members of the committee which were approved by them. Later the minutes of the subcommittee meeting held on 17-1-14 were distributed and were approved by the members.

In the meeting a total of 79 proposals were discussed. After deliberations the following decisions were arrived at

- Number of proposals approved : 2
- Number of approved subject to minor corrections : 76
- Number of proposal for which decision deferred : 1

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to Dr. C. Adithan, Member-Secretary within 15days. If the revision is satisfactory, the approval certificate will be issued after consulting the chairman of the committee. Otherwise, they need to submit 15 copies of proposal (Form 1A) to IEC for its approval. It will be considered as fresh proposal.

SI.No	Departments	SI.No	Departments
1.	Anatomy	15.	Endocrinology
2.	Bio-Chemistry	16.	Ophthalmology
3.	Physiology	17.	Radiotherapy
4.	Pharmacology	18.	Orthopaedics
5.	Pathology	19.	Obstetrics & Gynaecology
6.	Micro Biology	20.	Urology
7.	Clinical Immunology	21.	Plastic Surgery
8.	ENT	22.	Neuro Surgery
9.	Clinical Hematology	23.	Surgical Gastroenterology
10.	Medical Oncology	24.	Nephrology
11.	Anesthesiology & Critical Care	25.	P&SM
12.	Dermatology	26.	Surgical Oncology
13.	Medicine	27.	Cardiology
14.	Paediatrics	28.	Surgery

S.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
Anatomy				
1.	JIP/IEC/2014/1/204	Investigator: Dr.V.Gladwin, Assistant Professor, Dept. of Anatomy Co-Investigator: Dr.Ravi Philip Rajkumar, Associate Professor, Dept. of Psychiatry Dr.Nandeesh.H, Assistant Professor, Dept. of Biochemistry	Assessment of DNA Damage in patients with Dementia	Accepted with the following corrections: 1.Dementia patients comes under vulnerable population, and hence ICF from LAR is required in addition to from patients. 2.Separate consent form for healthy volunteers & patients Include Name, signature and address of witness 3.Healthy controls – define the criteria and from where they will be recruited 4.References should be included 5.Information regarding DNA sample storage needs to be given. 6.Confidentiality of records and participation-identity will not be revealed in publications. 7.ICF – to be changed as per format (English & Tamil)
2.	JIP/IEC/2014/1/205	Investigator: Dr.Adithya Gajanan Hegde, I year junior Resident, Dept. of Anatomy, Guide: Dr.Sarasu J, Associate Professor, Dept. of Anatomy Co-Guide: 1. Dr.RenukaSrinivasan, Professor and Head, Dept. of Ophthalmology 2. Dr. Shewade D. G., Professor, Dept. of Pharmacology, 3. Dr. Sasirekha R, Assistant Professor, Dept. of Obst. & Gynae.	Detection of Rh-D status of fetus in Rh -negative mother by non invasive prenatal diagnostic technique.	Accepted with the following corrections: 1.Need to mention about compensation for participation. 2.Mention additional blood will be collected for the study. 3.ICF – 11- include for unforeseeable risk and death. 4.Include references 5.ICF is having lots of information medical jargon – so relevant info needs to be given in simplified way Include Name, signature and address of witness 6.Provisions made for antenatal RhD injection after determining Rh status if necessary – funds need to be provided from the project before commencing the study-clarify standard of care regarding ante natal Rh D with concerned deciding authority 7.Under 18 pregnancy needs to excluded 8.ICF 1 & 2– to be changed as per format (English & Tamil) Include Name, signature and address of investigator
Biochemistry				
3.	JIP/IEC/SC/2013/5/434	Investigator: DR. Manoj Joseph, Junior Resident, Dept. of Biochemistry Guide:	Additional supplementation of water soluble vitamins in hypothyroidism: effects on	Accepted with the following corrections: 1.Mention that whether breakfast will be provided to patients as they have to come after fasting. 2. Mention post study benefit for placebo group.

		<ol style="list-style-type: none"> 1. Dr. Zachariah Bobby, Professor, Dept. of Biochemistry 2. Dr. Sadish Kumar @ Kamalanathan, Associate Professor, Dept. of Endocrinology 	biochemical profile and clinical outcome	<ol style="list-style-type: none"> 3. ICF 10 – clarify regarding compensation for participation 4. Mention vit supplements will be given during routine visits for check up and drug collection. 5. Clarification regarding storage of sample in ICF 6. Free treatment and compensation as per JIPMER guidelines. 7. ICF – 14 needs to be changed in English & Tamil <p>Include Name, signature and address of witness</p>
4.	JIP/IEC/2014/1/206	<p>Investigator: Dr. Prabhat, M.D Student, Dept. Of Biochemistry</p> <p>Guide: Dr.R. Soundravally, Associate Professor, Dept. Of Biochemistry</p> <p>Co-Guide: Dr. T. Kadiravan, Associate Professor, Dept. Of Medicine, Jipmer Dr.Rahul Dhodapkar, Asst. Prof., Dept. of Microbiology</p>	Effect of <i>carica papaya</i> leaf extract on platelet aggregation, membrane fluidity and p-selectin expression in dengue infection: a randomised controlled trial	<p><u>Not recommended in the present form as safety is not assured</u></p> <ol style="list-style-type: none"> 1. Allopathic practitioner as per Court judgement can not administer herbal extract, without having Siddha or Ayur practitioner as collaborators. 2. Only standardized and marketed herbal product should be used. Otherwise approval of DCGI is essential before starting the study. 3. Include Indian study in references
Physiology				
5.	JIP/IEC/2014/1/207	<p>Investigator: Dr.G.K.Pal, Professor & Head, Dept. of Physiology</p> <p>Co-Investigator: 1.Dr.T.S.Ravikumar, Director 2.Dr.Sitanshu Sekhar Kar, Associate Professor, Dept. of P&SM 3.Dr.J.Balachander, Professor, Dept.of Cardiology 4.Dr.V.Lalitha, SR, Dept. of Physiology 5.Dr.Pravati Pal, Professor, Dept. of Physiology</p>	Assessment of cardiovascular disease risks and role of yoga in reducing these risks in community an interventional study	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Under methodology – inclusion criteria – clarify lack of physical activity if it is mild, moderate and severe 2. Blood volume needs to be given in ml in the protocol 3. Protocol – Sl.No.11- Investigations need to be mentioned 4. Clarify regarding uniformity of yoga practices being ensured in all study subjects - make it 3 days under supervision in JIPMER and not to do at home to ensure uniformity and to avoid bias 5. Include two sets of consent forms for this study- (a) separate screening consent form for all screened in community (b) second consent form for the study subjects recruited (nested group). 6. Justify exclusion of alcoholics in the study. 7. ICF1 – pt 9- Discrepancy in English and Tamil version needs to be corrected 8. Free treatment and compensation as per JIPMER guidelines. 9. Can withdraw from study without assigning any reasons 10. Include Name, signature and address of witness

6.	JIP/IEC/2014/1/208	<p>Investigator: Dr. G. Sunil Naik, Junior Resident, Dept. of Physiology</p> <p>Guide: Dr G S Gaur, Professor, Dept. of Physiology</p> <p>Co-Guide: Dr G K Pal, Professor & Head, Dept. of Physiology.</p>	Effect of slow breathing exercise on stress score and correlation of stress score with resting heart rate variability and pulmonary functions in young healthy male volunteers.	<p>Accepted with the following corrections This study was approved by earlier IEC but now the investigator has been changed and few modifications have been made in the study.</p> <ol style="list-style-type: none"> Title has been changed by adding "correlation" in the title Justify exclusion of healthy female volunteers Mention the previous approval number Avoid medical jargon in Tamil ICF and revise it in simple language.
7.	JIP/IEC/SC/2013/5/450	<p>Investigator: Dr. Devi R. Nithiya, Junior Resident, Dept. of Physiology</p> <p>Guide: Dr. Pravati Pal, Professor, Dept. of Physiology,</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> Dr. Gunaseelan K., Associate Professor, Dept. of Radiotherapy, RCC Dr. G. K. Pal, Professor and Head, Dept. of Physiologys 	Effect of Yoga on Pulmonary, Cardiovascular, Metabolic functions and stress score in Post-mastectomy patients undergoing Radiotherapy: A Randomized Control Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> Mention asanas to be done in the protocol Mention participation is for 3 months Mention regarding compensation Mention that the participants will be benefited from their participation in the study and outline the benefits involved. Revise Informed consent forms part 1 as per format Clarify regarding when yoga module will be administered with radiotherapy session. Delete the line about storage of samples in ICF 2 in English and Tamil. Can withdraw from study without assigning any reasons Include Name, signature and address of witness Signature of investigator to be included
8.	JIP/IEC/2014/1/209	<p>Investigator: Dr. Danasegaran. M, Junior Resident, Dept. of Physiology</p> <p>Guide: Dr. G.K Pal, Professor & Head, Dept. of Physiology, Programme Director – ACYTER</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> Dr. Pravati Pal, Professor, Dept. of Physiology. Dr. Jayaprakash Sahoo, Assistant Professor, Dept. of Endocrinology. 	Effect of a yoga module on sympathovagal imbalance, oxidative stress, inflammatory markers, insulin resistance, and lipid profile in type 2 diabetes in males.	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> Justification for exclusion of females in the study as diabetes is seen in females too.

Pharmacology				
9.	JIP/IEC/2014/1/210	Investigator: Dr. P. Indumathi, I Year MD, Junior Resident. Dept. of Pharmacology Guide: De.B.Gitanjali, Professor, Dept. of Pharmacology Co-Guide: Dr.Gunaseelan.K, Associate Professor, Dept. of Radiotherapy	A randomized double - blind controlled study comparing the efficacy and safety of controlled release morphine with immediate release morphine for cancer pain in palliative care patient	Accepted with the following corrections: 1. Mention regarding compensation for the participants as blood samples are taken for 6 times.
Pathology				
10.	JIP/IEC/2014/1/211	Investigator: Dr.Rajesh NG, Associate Professor, Dept. of Pathology Co-Investigator: 1. Dr.Bhawana A Badhe, Professor & Head, Dept. of Pathology 2. De.Debdatta Basu, Professor, Dept. of Pathology 3. Dr.Biswajith Dubashi, Associate Professor, Dept. of Oncology 4. Dr.Suresh Chandra Pradhan, Professor & Head, Dept. of Pharmacology	NPM1 mutataion and its association with Acute Myeloid Leukemia	Accepted with the following corrections: 1. Mention the date JSAC approval 2. Compensation needs to be mentioned for participation and compensation for unforeseeable risk as per JIPMER guideline – Change the discrepancy regarding compensation in English and Tamil versions 3. Confidentiality of participation needs to be mentioned 4. Investigator signature needs to be added in Tamil version
11.	JIP/IEC/2014/1/212	Investigator: Dr. Surendra Kumar Verma, Professor, Dept. of Pathology Co-Investigator: Dr. Venkatesh S Madhugiri, Associate Professor, Dept. of Neuro Surgery	Expression of leptin and its receptors in Brain Neoplasms	Accepted with the following corrections: 1. Mention regarding agreement for getting samples from NIMHANS 2. Revision of Tamil ICF similar to English ICF 3. Information regarding sample storage needs to be mentioned.
Microbiology				
12.	JIP/IEC/SC/2013/5/459	Investigator: Dr. Geni.V.G, 1 st year JR, Dept. of Microbiology Guide: Dr.Rakesh Singh, Associate Professor, Dept. of Microbiology	Role of p24 Antigenemia in Early Detection of HIV infection among Couples	Approved
Clinical Immunology				
13.	JIP/IEC/SC/2013/5/433	Investigator: Dr. Usdadiya Jignesh Babulal, DM SR Clinical Immunology Guide:	Comparison of Combination Disease Modifying Drugs (DMARDs) with Single Drug (Methotrexate) Therapy in	Accepted with the following corrections: 1. Mention safety of drug in the methodology 2. Clarify the term unprotected females in exclusion criteria

		Dr. Vir Singh Negi, Professor & HOD, Dept. of Clinical Immunology Co-Guide: Dr. A. Ramesh, Assistant Professor, Dept. of Radiodiagnosis	Early Rheumatoid Arthritis.	3. Clarify regarding compensation and foreseeable as well as unforeseeable risks
14.	JIP/IEC/SC/2013/5/435	Investigator: DR. Sonal Mehra, DM SR, Dept. of Clinical Immunology Guide: DR. Vir Singh Negi, Professor, HOD, Dept. of Clinical Immunology Co-Guide: 1. DR. R.P. Swaminathan, Professor, Head, Dept. of Medicine and Dept. of Nephrology 2. DR. Rajesh N G, Assistant Professor, Dept. of Pathology	Comparison of intravenous low dose versus high dose cyclophosphamide as induction therapy in the treatment of proliferative lupus nephritis	Accepted with the following corrections: 1. Co-guide signatures needs to be obtained 2. ICF - Clarify regarding compensation and foreseeable as well as unforeseeable risks 3. For 16-17 yrs subjects – include assent form in addition to consent from parents / LAR 4. Clarify information regarding storage of samples in both English and Tamil
ENT				
15.	JIP/IEC/SC/2013/5/428	Investigator: Dr. Natarajan, Junior Resident, Dept. of ENT Guide: Dr. S. Gopalakrishnan, M.S., D.L.O, Professor, Dept. of ENT Co-Guide: 1. Dr. Sunil Kumar Saxena, M.S., Professor & Head, Dept. of ENT, 2. Dr. Pradipta Kumar Parida, M.S, Assistant Professor, Dept. of ENT	Comparison of Triamcinolone and Mitomycin C nasal pack in Functional Endoscopic Sinus Surgery – A Randomized Clinical Trial	Accepted with the following corrections: 1. Clarify regarding the efficacy of triamcinolone from previous studies 2. ICF – 8 - mention the answer for expected risk 15 – clarify on alternative treatment available 3. Foreseen and unforeseen risks should be a separate question and death should be a separate question 4. Revise ICF completely in order with prescribed format
16.	JIP/IEC/2014/1/213	Investigator: Dr. Karthikeyan, JR, Dept. of ENT Guide: Dr. Pradipta Kumar Parida, M.S, Associate Professor, Dept. of ENT Co-Guide: Dr. Sunil Kumar Saxena M.S., Professor & Head, Dept. of ENT	Comparison of gloved vs ungloved merocel as nasal pack after septoplasty – A Randomized clinical trial	Accepted with the following corrections: 1. Parameters of the study shown in the presentation needs to be included in the study protocol 2. ICF – clarify regarding compensation, foreseeable and unforeseeable risks 3. ICF- II – should obtain consent from participant 4. Signature of investigator 5. Name, signature and address of witness
17.	JIP/IEC/2014/1/214	Investigator: Dr Arun Alexander, Associate Professor, Dept. of ENT Co-Investigator: Dr Medha R, Associate Professor, Dept. of Biochemistry	Assessment of cytokine profile in patients with nasal polyposis	Accepted with the following corrections: 1. ICF(Tamil) – 13 – should be similar to English; mention patients can withdraw without giving any reasons

Clinical Hematology				
18.	JIP/IEC/2014/1/228	<p>Investigator: Deepak Charles, Senior Resident, Clinical hematology</p> <p>Guide / Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr.Tarun kumar Dutta, Professor, Dept. of Medicine & division of hematology 2. Dr.S.Mahadevan, Professor, Dept. of Pediatrics 3. Dr. P. Nalini, Ex Professor, Dept. of Pediatrics, President Hemophilia Society of India, Pondicherry Chapter 4. Dr. Niranjan Biswal, Professor, Dept. of Pediatrics 5. Dr. Debdatta Basu, Professor, Dept. of Pathology 6. Dr.A.Ramesh, Assist. Professor, Dept. of Radiodiagnosis 	Efficacy of once weekly prophylactic therapy in prevention of clinically significant bleeds in patients with severe hemophilia A	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. To include Factor VIII in title and objectives 2. To clarify discrepancy in the factor VIII dose (20 / 25 IU/Kg) 3. Remove the point 12 in protocol on use of storage samples
Medical Oncology				
19.	JIP/IEC/2014/1/229	<p>Investigator: Dr.Ranjith Kumar CS, SR, Dept. of Medical Oncology</p> <p>Guide : Dr.Biswajit Dubashi, Associate Professor, Dept. of Medical Oncology</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr.Smitakayal, Assistant Professor, Dept. of Medical Oncology 2. Dr.S.Vinod Kumar, HOD, Dept. of Pulmonary Medicine 3. Dr.Deepak Bharathi, Assistant Professor, Dept. of Radio Diagnosis 	Comparison of efficacy of Gefitinib Versus Pemetrexed in Metastatic Lung Cancer maintenance therapy – A Randomized trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1.Date of JSAC approval needs to be mentioned 2.Mention EORTC will be used for assessing QoL in the study protocol 3.Obtain signatures from co-investigators 4.Compensation, foreseeable and unforeseeable risks needs to be mentioned 5.Mention regarding freedom to withdraw from the study at any time, expected benefits and future risks 6.Clarity discrepancy regarding level of risk –mention it as more than minimal risk 7.Remove storage of biological samples from ICF 8.Remove IC will be obtained from parents as the participants of the study are above 18 yrs 9.Purpose of the study needs to be corrected in the protocol
Anesthesiology & Critical Care				

20.	JIP/IEC/2014/1/215	<p>Investigator: Dr Suhas P, Fellowship in Critical Care, Senior Resident, Dept. of Anaesthesiology and Critical Care</p> <p>Guide: Prof Pankaj Kundra, Professor and HOD, Dept. of Anaesthesiology and Critical Care</p> <p>Co-Guide: Dr. Anusha Cherian, Asst. Professor, Dept. of Anaesthesiology and Critical Care</p>	Comparison of the efficiency of polyurethane cuffed endotracheal tube with conventional endotracheal tubes on VAP incidence in critically ill patients – a randomized clinical trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Compensation, foreseeable and unforeseeable risks needs to be mentioned 2. Use of abbreviation in title needs to be expanded within bracket 3. Modify the line on thanking the patient for participating with keen interest and for asking to clarify doubts as the patients are in ICU 4. IC should also be obtained from LAR as they are vulnerable population
21.	JIP/IEC/2014/1/216	<p>Investigator: Dr. Ayyappan. C, Junior Resident, Dept. of Anesthesiology & Critical Care</p> <p>Guide: Dr. Sandeep Kumar Mishra, Assistant professor, Dept. of Anesthesiology & Critical Care,</p> <p>Co-Guide: Dr. Satyen Parida, Assistant Professor, Dept. of Anesthesiology & Critical Care</p>	Time course of psychomotor recovery after intravenous dexmedetomidine infusion as a part of balanced anaesthetic technique: A randomized, double-blind study	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify issue on regular follow up as patient will be in post operative ward 2. Mention free treatment will be given to the patient 3. Mention the ethical issues involved in the study & level of risk involved 4. Revise ICF completely after discussion with member secretary
22.	JIP/IEC/2014/1/217	<p>Investigator: Dr. Sivasankar S, Junior Resident, Dept. of Anesthesiology and Critical Care</p> <p>Guide: Dr. Satya Prakash M V S, Associate Professor, Department of Anesthesiology and Critical Care</p> <p>Co-Guide: Dr. Lenin Babu E, Associate professor, Department of Anesthesiology and Critical Care</p>	Comparing the medication acceptance of intranasal midazolam administered by parents and doctors in children	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify the age group in Tamil version compared to English version 2. Include assent form in addition to parent / LAR consent form 3. Change guardian to legal guardian in the consent form 4. In the protocol mention drug should be administered by parents only under the supervision of anesthetist
23.	JIP/IEC/2014/1/218	<p>Investigator: Dr. Srinivasan R, Junior Resident First Year, Dept. of Anesthesiology and Critical Care</p> <p>Guide: Dr. Hemavathi Balachander, Professor, Dept. of Anesthesiology and Critical Care</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Sandeep Kumar Mishra, Associate professor, Dept. of Anesthesiology and Critical Care, 2. Dr. Prasanna Udipi Bidkar, Associate professor, Dept. of Anesthesiology and 	Evaluation of cuff and tube tip position in microcuff pediatric endotracheal tubes.	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. "Exemption will be asked for obtaining informed consent" - needs to be removed from the protocol 2. Include investigator signature in the declaration page 3. Include for age <18 yrs consent will be obtained from parents / LAR

		Critical Care		
24.	JIP/IEC/2014/1/219	<p>Investigator: Dr.Balaji.V, MD, Dept. of Anaesthesiology</p> <p>Guide:</p> <ol style="list-style-type: none"> 1. Dr. Pankaj Kundra, Professor & H.O.D, Dept. of Anaesthesiology and Critical Care 2. Dr. Adithan C, Professor & H.O.D, Dept. of Clinical Pharmacology 3. Dr.V.Stalin, Assistant Professor, Dept. of Anaesthesiology 4. Dr. Nataraj AR, Assistant Professor, Dept. of Orthopaedics 	Concentration of ceftriaxone at the surgical site following systemic and isolated upper limb injection.	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify the ethical issues involved & mention the level of risks involved 1. Include free treatment will be provided 2. Compensation for foreseeable and unforeseeable risks as per JIPMER guideline needs to be mentioned 3. Rationale for dose selection as well as cut offs for height and weight needs to be mentioned in the protocol
25.	JIP/IEC/SC/2013/5/449	<p>Investigator: Dr. Sidhesh Bharne, Fellow in Cardiac and Neuro anaesthesia, Dept. of Anaesthesia and Critical Care</p> <p>Guide:</p> <ol style="list-style-type: none"> 1. Dr. Ashok Badhe, Professor, Dept. of Anesthesia and Critical Care 2. Dr. Prasanna Bidkar, Assistant Professor, Dept. of Anaesthesia and Critical Care, 3. Dr. Satyen Parida, Assistant Professor, Dept. of Anaesthesia and Critical Care, 4. Dr. Ramesh, Assistant Professor, Dept. of Neurosurgery, 	Comparison of labetalol and bupivacaine scalp block on the hemodynamic and entropy changes following skull pin application – a randomized clinical trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Change level of risk to minimal risk 2. Revise consent form according to format 3. Delete “not applicable” and clarify answers for unforeseeable risk and freedom to withdraw from the study 4. Add references at the end of the protocol
26.	JIP/IEC/2014/1/220	<p>Investigator: Dr.Perika Tilak, M.D., Dept. of Anaesthesiology</p> <p>Guide: Dr. Suman Lata, Associate Professor, Dept. of Anaesthesiology</p> <p>Co-Guide: Dr.Lenin Babu, Associate Professor, Dept. of Anaesthesiology</p>	Psychomotor recovery of dexmedetomidine compared With propofol after sedation during spinal anaesthesia	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Justify what is the need for this study as previous studies already exist and specify what is new in this study. 2. Mention the level of risk 3. Mention risks as encountered in any regular surgical procedure – delete “no risk” 4. Expected benefit for the patient in the study needs to be clarified 5. Include title of the study in the signature page, get fresh signatures and resubmit the proposal 6. Clarify regarding study related injury and mention if any additional risks involved.
27.	JIP/IEC/2014/1/221	<p>Investigator: Dr.Guru K, M.D. Anaesthesiology</p> <p>Guide:</p>	Nalgesic efficacy of intravenous dexmedetomidine versus paracetamol for post	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Justify the reason for including maxillo facial surgery alone in the protocol

		Dr. Adinarayanan S, Asst. Prof, Dept. of Anaesthesiology Co-Guide: 1. Dr. Satyen Parida, Asst. Prof, Dept. of Anaesthesiology 2. Dr. Hemavathi Balachander Professor, Dept. of Anaesthesiology 3. Dr. Krishnan B, Asst. Prof, Dept. of Dentistry	operative pain relief in maxillofacial surgery : Randomized double blind controlled trial	2. Mention how pain will be assessed in the protocol 3. Clarify regarding compensation for participation 4. Revise ICF II (English) so that it comes in a single page 5. Storage of biological material to be deleted
28.	JIP/IEC/2014/1/222	Investigator: Dr.Mallikharjuna Payyavula, Junior Resident, Dept. of Anesthesiology & Critical Care Guide: Dr.Ashok Shankar Badhe, Professor & Former HOD, Dept. of Anesthesiology & Critical Care Co-Guide: 1. Dr. P.Sakthi Rajan, Assistant Professor, Dept. of Anesthesiology & Critical Care 2. Dr.Prasanna Bidkar, Assistant Professor, Dept. of Anesthesiology & Critical Care	Hemodynamic stability in patients undergoing micro laryngeal surgery under general anesthesia-comparison of Dexmedetomidine and Fentanyl a randomized double blind controlled clinical trial	Accepted with the following corrections: 1. Mention the level of risk – Delete “ No Risk” 2. Compensation for foreseeable and unforeseeable risks as per JIPMER guideline needs to be mentioned 3. Tamil translation needs to be revised in line with English ICF
29.	JIP/IEC/2014/1/223	Investigator: Dr. Pankaj Kumar, M.D., , Dept. Of Anesthesiology and critical care Guide: Dr. A. Vasudevan, Assistant Professor, Dept. of Anesthesiology and Critical Care Co-Guide: Dr. P. Sakthi Rajan, Assistant Professor, Dept. of Anesthesiology and Critical Care	Comparison of direct and guide-wire assisted techniques of radial artery cannulation in patients posted for emergency surgery- a randomized clinical trial.	Accepted with the following corrections: 1. ICF – pt 13 - Compensation for foreseeable and unforeseeable risks needs to be mentioned 2. Mention the measures to be taken if failure occurs during radial artery cannulation 3. Clarify regarding storage of biological sample 4. Clarify regarding confidentiality that results will be shared after decoding identity of patient 5. Signature page needs to be resubmitted
30.	JIP/IEC/2014/1/224	Investigator : Dr.Makireddy Rekha, M.D., Dept. Of Anaesthesiology Guide: Dr. Anusha Cherian, Assistant Professor, Dept. of Anaesthesiology Co-Guide: Dr.Lenin Babu, Associate Professor, Dept. of Anaesthesiology	Correlation between correctly sized uncuffed Endotracheal tube and ultrasonographically determined sub glottic diameter in pediatric population	Accepted with the following corrections: 1. Change the period of study from 2013 to 2014 2. Include Guide’s signature 3. ICF – include signature of parent or LAR (Legally acceptable representative) 4. Mention the level of risk – Delete “No Risk”
31.	JIP/IEC/2014/1/225	Investigator: Dr. Ranjith Kumar.M, M.D., Dept. of Anesthesiology and Critical Care	Circulatory changes during positioning in patients undergoing craniotomy in	Accepted with the following corrections: 1. Signature of the guide needs to be included 2. Mention the level of risk – Delete “same risk”

		Guide: Dr. Bidkar Prasanna Udupi, Assistant Professor, Dept. of Anaesthesiology & Critical care. Co-Guide: 1. Dr. Praveen Talawar, Assistant Professor, Dept. of Anaesthesiology & Critical care. 2. Dr. Roopesh Kumar V R, Additional Professor, Dept. of Neurosurgery	sitting position	3. Compensation for foreseeable and unforeseeable risks as per JIPMER guideline needs to be mentioned
Cardiology				
32.	JIP/IEC/SC/2013/5/445	Investigator: Dr. Krishna Sarin M S, Senior Resident, Dept. of Cardiology Guide: Dr.Santhosh Satheesh, Additional Professor and Head, Dept. of Cardiology, Co-Guide: 1. Dr.Balachander J, Professor, Cardiology& Medical Superintendent 2. Dr.Patrick Henry, Professor, Cardiology, Lariboisiere Hospital, Paris, France 3. Dr.Ajith Ananthkrishnapillai, Associate Professor, Cardiology 4. Dr.Raja J Selvaraj, Associate Professor, Cardiology 5. Dr Mahesh Kumar S, Associate Professor, Cardiology	A cross-sectional study to compare atherosclerotic risk factors, coronary artery diameters and disease severity in two tertiary care centers catering to south Indian and Caucasian populations	Accepted with the following corrections: 1.Change the period of study from Jan 2014 to after IEC approval. 2. Approval will be given only for study involving Indian subjects.
33.	JIP/IEC/2014/1/226	Investigator: Dr Amar Nath Upadhyay, Senior Resident, Dept. of Cardiology Guide / Co-Guide: Dr. Ajith A , Assistant Professor ,Dept. of Cardiology	Techniques and outcomes of percutaneous closure of complex ostium secundum atrial septal defects: a prospective study	Accepted with the following corrections: 1. Certify that all procedures used in this study are professionally acceptable and are standardized.
34.	JIP/IEC/2014/1/227	Investigator: BhupendraVerma, Senior resident, cardiology Guide: Dr.Mahesh Kumar, Assistant Professor, Dept. of cardiology Co-Guide: 1. Prof.Balachander Jayaraman, Professor, Cardiology 2. Dr.Santhosh Satheesh, Associate Professor	Comparison of contrast enhanced low-dose dobutamine stress echocardiography with SPECT in assessment of myocardial viability and prediction of improvement in left ventricular function after revascularisation	Accepted with the following corrections: 1. Clarify regarding the level of risk and benefit to the patient. 2. Clarify regarding compensation for foreseeable and unforeseeable risks. 3. Mention free treatment will be provided for study related injury.

		<p>and Head, Cardiology</p> <p>3. Dr.Nandini Pandit, Additional Professor and head, Nuclear Medicine</p> <p>4. Dr. Raja Selvaraj, Assistant Professor, Cardiology</p> <p>5. Dr.Ajith AnantkrishnaPillai, Assistant Professor, Cardiology</p>		
Surgery				
35.	JIP/IEC/2014/1/230	<p>Investigator: Dr. A.S. Sanjeev, Junior Resident, General Surgery</p> <p>Guide: Dr. S. Jagdish, Professor, General Surgery</p> <p>Co-Guide: Dr. Suresh Kumar S., Assistant Professor, General Surgery</p>	Pressure Off-Loading Device Vs. Conventional wet gauze dressing in treatment of Neuropathic Plantar Ulcers- A Prospective Randomized Controlled Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify the level of risk in protocol & ICF - Change level of risk to minimal risk. 2. Clarify on study related injury and mention free treatment will be provided for such injury. 3. Clarify on expected, foreseeable and unforeseeable risks.
36.	JIP/IEC/2014/1/231	<p>Investigator: Dr. Suresh Kumar S, Assistant Professor, Dept. of Surgery</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Sreenath Gubbi Samanna, Assistant Professor, Dept. of surgery 2. Dr. Mathews James, Junior Resident, Dept. of Surgery 3. Dr. Sanjeev A S, Junior Resident, Dept. of Surgery 	Suture Skin Closure vs. Staple Skin Closure in Elective and Emergency Midline Laparotomy Incisions – A Randomized Controlled Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on confidentiality of patient information. 2. Clarify the level of risk in protocol & ICF. 3. Clarify on study related injury and mention free treatment will be provided for such injury. 4. Clarify on expected, foreseeable and unforeseeable risks.
37.	JIP/IEC/2014/1/232	<p>Investigator: Dr. Suresh Kumar, Assistant Professor, Dept. of Surgery</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Manwar Ali S, Assistant Professor, Dept. of surgery 2. Dr. Sanjeev A S, Junior Resident, Dept. of Surgery 3. Dr. Mathews James, Junior Resident, Dept. of Surgery 	Comparison of skin closure technique with Nylon Suture, Stapler and Glue in Lichtenstein tension free hernia meshplasty- A Multi - Armed Randomized Controlled Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on confidentiality of patient information. 2. Clarify the level of risk in protocol & ICF. 3. Revise ICF (English and Tamil version) in line with standard format. 4. Clarify regarding compensation on expected, foreseeable and unforeseeable risks. 5. Delete regarding storage of biological samples for future purpose.
38.	JIP/IEC/2014/1/233	<p>Investigator: Dr. Prasad Yerra, Junior Resident, Dept. of Surgery</p> <p>Guide / Co-Guide:</p>	Effect of perioperative hyperoxygenation on surgical site infection in patients undergoing emergency	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Include assent form and consent form from parents / LAR. 2. Clarify on level of risk in protocol & ICF.

		<ol style="list-style-type: none"> 1. Dr. Sarath Chandra Sistla, Professor, Dept. of General Surgery 2. Dr. Punkaj Kundra, Professor and head, Dept. of Anaesthesiology 3. Dr. K. Balamourougan, Assistant professor, Dept. of General Surgery 	abdominal surgery- A Randomized Clinical Trial	<ol style="list-style-type: none"> 3. Include free treatment will be provided for study related injury. 4. Clarify regarding compensation on expected, foreseeable and unforeseeable risks.
39.	JIP/IEC/2014/1/234	<p>Investigator: Arindam Mondal, Junior Resident, Dept. of General Surgery</p> <p>Guide / Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. S. Manwar Ali, Assistant Professor, Dept. of Surgery 2. Dr. Sarath Chandra Sistla, Professor, Dept. of Surgery 3. Dr. S. Elangovan, Professor, Dept. of Radiodiagnosis 	Effect of Incisional Negative Pressure Wound Therapy in reducing wound complications following repair of incisional hernia: A Randomized Controlled Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on level of risk in protocol & ICF – change it to minimal risk. 2. Include free treatment will be provided for study related injury. 3. Clarify regarding compensation on expected, foreseeable and unforeseeable risks.
40.	JIP/IEC/2014/1/235	<p>Investigator: Dr. Parth Pratim Pasayat, 1st Year Post Graduate Student, Dept. of Surgery</p> <p>Guide / Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. D. Kadambari, Professor, Dept. of Surgery 2. Dr. A.S. Badhe, Sr. Professor, Dept. of Anaesthesiology. 3. Dr.S.C.Pradhan, Professor and Head, Dept. of Pharmacology 4. Dr. Suresh Kumar S, Assistant Professor, Dept. of Surgery 	Efficacy of tumescent anaesthesia technique for modified radical mastectomy - a randomized clinical trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Date of JSAC approval needs to be mentioned.
41.	JIP/IEC/2014/1/236	<p>Investigator: Dr. Mathews James, Junior resident, Dept. of Surgery</p> <p>Guide: Dr. Suresh Kumar, Assistant Professor, Dept. of Surgery</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Jagdish S, Professor, Dept. of Surgery 2. Dr. Vikram Kate, Professor, Dept. of Surgery 	Primary skin closure vs. Delayed primary skin closure in reducing Surgical Site Infection(SSI) in dirty midline abdominal operative wounds - A randomized controlled trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on level of risk in protocol & ICF. 2. Include free treatment will be provided for study related injury. 3. Clarify regarding compensation on expected, foreseeable and unforeseeable risks.
42.	JIP/IEC/2014/1/237	<p>Investigator: Dr. Ashok Kumar Sahoo, M.S (GENERAL SURGERY)</p> <p>Guide:</p>	"Hybrid therapy versus sequential therapy for eradication of Helicobacter pylori – A randomized trial".	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on level of risk in protocol & ICF- change to "minimal risk". 2. Clarify on expected risk as well as compensation

		Dr. Vikram Kate, Professor, Dept. Of Surgery Co-Guide: 1. Dr. Sreenath G S, Assistant Professor, Dept. Of Surgery 2. Dr. Jharna Mandal, Assistant Professor, Dept. Of Microbiology		for participation, expected, foreseeable, unforeseeable risks, disability and death as per JIPMER guidelines.
43.	JIP/IEC/2014/1/238	Investigator: Dr. Nelson.T, Junior Resident, Department of Surgery Guide: Dr. Vikram Kate, Professor, Department of Surgery Co-Guide: Dr. GS Sreenath, Assistant professor, Department of Surgery	A randomized clinical trial of early versus conventional stoma closure following bowel surgery.	Accepted with the following corrections: 1. Change the duration of study from 2013 to after obtaining IEC approval. 2. Clarify on level of risk in protocol & ICF- change to "minimal risk". 3. Clarify on expected risk to the patients.
Dermatology				
44.	JIP/IEC/2014/1/239	Investigator: Dr. Rashmi Kumari, Assistant professor, Dept. of Dermatology & STD Co-Investigator: 1. Dr. D.M.Thappa, Professor, Dept. of Dermatology & STD 2. Dr. Nidhi Singh, Senior resident, Dept. of Dermatology & STD 3. Dr. Rajesh Nachiappa, Assistant professor, Dept. of Pathology 4. Dr. Rakesh Singh, Assistant professor, Dept. of Microbiology	Factors affecting the severity of seborrheic dermatitis	Accepted with the following corrections: 1. ICF – Include treatment for research related injury will be provided 2. Clarify regarding compensation for inconvenience and unforeseeable risks 3. Delete third party involvement in the study 4. "Adverse effects due to concomitant medications" – need to be removed 5. Include references at the end
45.	JIP/IEC/2014/1/240	Investigator: Dr. Perumal. M, Junior Resident, Dept. of Dermatology and STD Guide: Dr. Rashmi kumari, Assistant Professor, Dept. of Dermatology and STD Co-Guide: Dr. D. M. Thappa, Professor , Dept. of Dermatology and STD	Efficacy and safety of Er:YAG laser in comparison with microdermabrasion in facial acne scarring : A randomized clinical trial.	Accepted with the following corrections: 1. ICF - Clarify regarding compensation for inconvenience and unforeseeable risks 2. Mention study will be conducted as per ICMR guidelines 3. Revise ICF Tamil version
46.	JIP/IEC/2014/1/241	Investigator: Dr. D. M. Thappa, Professor, Dept. of Dermatology	"Periorbital pigmentation and insulin resistance: Are they related?"	Accepted with the following corrections: 1. ICF – Delete the phrase "compensation for participation will be provided"

		Co-Investigator: Dr.Laxmisha Chandrashekar, Associate Professor, Dept. of Dermatology Dr. Medha R., Associate Professor, Dept. of Biochemistry Dr.Nidhi Singh, Assistant Professor, Dept. of Dermatology		
47.	JIP/IEC/2014/1/242	Investigator: Dr.Laxmisha Chandrashekar, Associate professor, Dept. of dermatology Co-Investigator: 1. Dr. Medha R., Associate professor, Dept. of Biochemistry 2. Dr. D. M. Thappa, Professor, Dept. of Dermatology	Assessment of biomarkers and HLA status in pemphigus	Accepted with the following corrections: 1. ICF – Delete the phrase “compensation for participation will be provided” 2. ICF- Q11- Add the phrase “including death” in the compensation for unforeseeable risk.
48.	JIP/IEC/2014/1/243	Investigator: Dr.Laxmisha Chandrashekar, Associate Professor, Dept. of Dermatology Co-Investigator: 1. DR. Medha R., Associate Professor, Dept. of Biochemistry 2. Dr. D. M. Thappa, Professor, Dept. of Dermatology 3. Dr. P. H. Ananthanarayanan, Senior Professor, Dept. of Biochemistry	Association of tumour necrosis factor- α (TNF-a) promoter polymorphism with treatment outcome of non-segmental vitiligo in South Indian population.	Accepted with the following corrections: 1. ICF – Delete the phrase “compensation for participation will be provided” 2. ICF- Q11- Add the phrase “including death” in the compensation for unforeseeable risk. 3. Delete “biological samples will be stored” clause in ICF-2 (English & Tamil)
Medicine				
49.	JIP/IEC/2014/1/244	Investigator: Dr Pramod Sagar B K, Junior Resident, Dept. of Medicine Guide / Co-Guide: 1. Dr Chanaveerappa Bammigatti, Associate Professor, Dept. of Medicine 2. R P Swaminathan, Professor and HOD, Dept. of Medicine	Comparison of two Anti Snake Venom protocols in hemotoxic snake bite: A randomized trial.	Accepted with the following corrections: 1. Need to get Medical superintendent permission before starting the study. 2. Clarify regarding maintenance of confidentiality as it involves medico-legal cases. 3. ICF (Tamil) – Mention the reply for no. 8 as per English ICF 4. Clarify regarding expected benefit to the patient and compensation for any disability as per JIPMER guidelines 5. Clarify regarding storage of samples for future purpose 6. Mention that while sharing information identity of the patient will not be revealed
50.	JIP/IEC/2014/1/245	Investigator: : Dr K Venkata Anudeep, Junior Resident,	“A study of gastric emptying by gastric scintigraphy in patients	Accepted with the following corrections: 1. Resubmit the proposal for next IEC meeting

		Dept. of Medicine Guide: Dr Vinod KV, Associate Professor, Dept. of Medicine. Co-Guide: 1. Dr. Dhanapathi H, Assistant Professor, Dept. of Nuclear Medicine 2. Dr. Nandini Pandit, Additional Professor, Dept. of Nuclear medicine 3. Dr. Vivek sharma, Assistant Professor, Dept. of Physiology 4. Dr. T.K.Dutta, SeniorProfessor, Dept. of Medicine	with type 2 diabetes mellitus and its correlation with symptoms”	
51.	JIP/IEC/2014/1/246	Investigator: : Dr.Ganthala Paul Kiran, JR, Dept. of Medicine Guide: Dr.Jyoti Wadhwa, Associate Professor, Dept. of Medicine Co-Guide: Dr.Abdoul Hamide, Professor, Dept. of Medicine Dr.Nandini Pandit, Additional Professor, Dept. of Nuclear Medicine	“Clinical profile and regional cerebral blood flow assessment in migraine patients using Tc99m-ECD SPECT”	Accepted with the following corrections: 1. Include signature of investigator in declaration page 2. Mention that while sharing information identity of the patient will not be revealed
Paediatrics				
52.	JIP/IEC/2014/1/247	Investigator: Dr. Reena Gulati, Assistant Prof. Dept of Pediatrics Co-Investigator: 1. Dr. B. Vishnu Bhat, Prof. and Head, Dept. of Pediatrics 2. Dr. Sarita Agarwal, Professor of Medical Genetics, SGPGIMS, Lucknow.	Study on genome wide analysis of sub-microscopic genetic aberrations in children with idiopathic intellectual disability/multiple congenital anomalies.	Accepted with the following corrections: 1. Clarify on the validation of the methodology 2. Clarify on the expected benefits to the parents of the child and to the child 3. Suggested to include parents and siblings in the genetic study 4. Clarify if clinical features of intellectual disability/multiple congenital anomalies are the same 5. Include and in the title instead of oblique 6. List the known intellectual disability that will be looked for in the study 7. ICF- Mention the answer to treatment will be provided free of cost
53.	JIP/IEC/SC/2013/5/427	Investigator:	Comparison of oral	Accepted with the following corrections:

		Dr .Bharathi B, Senior Resident, DM neonatology – Iyr Guide: Dr. Vishnu Bhat B, Professor & HOD , Dept. of Paediatrics Co-Guide: 1. Dr. Nivedita Mondal, Assistant Professor, Dept. of Pediatrics 2. Dr Mahesh, Assistant Professor, Dept. of cardiology	paracetamol versus ibuprofen for PDA closure in preterms – a randomized controlled single blinded study	Approval subject to DCGI permission
54.	JIP/IEC/2014/1/248	Investigator: Dr . Ganapathi Suryanarayana, Junior resident, Dept. of paediatrics Guide: Dr. Mahadevan. S, Professor & Head, Dept. of Pediatrics, Co-Guide: 1. Dr. Sriram Krishnamurthy, Associate Professor, Dept. of Pediatrics, 2. Dr. Zachariach Bobby, Professor, Dept. of Biochemistry	To study Clinical effects of N-acetylcysteine on Acute Kidney Injury and other serious morbidities in children with snake envenomation: A phase II trial study	Accepted with the following corrections: 1. Approval subject to DCGI permission and Medical superintendent permission before starting the study. 2. Clarify regarding compensation for participation.
55.	JIP/IEC/2014/1/249	Investigator: DR. Vaishnavi. R, Junior Resident, Dept. of Pediatrics Guide / Co-Guide: DR. Sriram Krishnamurthy, Associate Professor, Dept. of Pediatrics	Body weight-based prednisolone versus body surface area-based prednisolone regimen for induction of remission in children with nephrotic syndrome.	Accepted with the following corrections: 1. Mention how often response and relapse will be assessed in the protocol. 2. ICF – clarify regarding compensation for unforeseeable risk.
56.	JIP/IEC/2014/1/250	Investigator: Dr. Shreya Sharma, Junior Resident, Dept. of Pediatrics Guide: Dr. Niranjana Biswal, Professor, Dept. of Pediatrics Co-Guide: 1. Dr. Adhisivam B, Associate Professor, Dept. of Pediatrics 2. Dr. MEDHA R, Associate Professor, Dept. of Biochemistry 3. Dr. Sadish Kumar@ Kamalanathan, Associate Professor, Dept. of Endocrinology	Role of Oral Cholecalciferol as an adjunctive Therapy in Type 1 Diabetes Mellitus : A Randomized Controlled Trial	Accepted with the following corrections: 1. Clarify regarding the frequency of vitamin D dose with evidence. 2. Mention regarding withdrawal of patients if toxicity occurs with Vit D. 3. Include “To rule out toxicity vitamin D level will be measured at 3 months on follow up”. 4. Exclude children for whom self blood glucose monitoring cannot be done by parents

57.	JIP/IEC/2014/1/251	<p>Investigators: Dr Vishnu Bhat B, Professor and Head, Dept. of Pediatrics</p> <p>Co-investigators: Dr Adhisivam B, Assistant Professor, Dept. of Pediatrics Dr Shruthi K Bharadwaj, Senior Resident, Dept. of Pediatrics</p>	Randomised trial of BCG in low-birth-weight babies < 2000 gram (BLOW trial)	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify the level of risk 2. Clarify on expected risks to the children.
58.	JIP/IEC/2014/1/252	<p>Investigators: Dr Shruthi K Bharadwaj, Senior Resident, Division of Neonatology, Dept. of Pediatrics</p> <p>Co-investigators: Dr B Vishnu Bhat, Professor and Head, Division of Neonatology, Dept. of Pediatrics Dr Nivedita Mondal, Assistant Professor, Division of Neonatology, Dept. of Pediatrics</p>	Levetiracetam vs Phenobarbitone for the control of neonatal seizures: A double blind randomised controlled Trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify the level of risk 2. Clarify on expected risks to the children.
Endocrinology				
59.	JIP/IEC/SC/2013/5/441	<p>Investigator: Karthik Balachandran, Senior Resident, Dept. of Endocrinology</p> <p>Guide: Dr.Sadishkumar Kamalanathan, Assistant professor, Dept. of Endocrinology,</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr.Jayaprakash Sahoo, Assistant professor , Dept. of Endocrinology 2. Dr.A.K.Das, Professor and head of Department, Dept. of Endocrinology, 3. Dr. Sridhar M.G., Professor and Head, Dept. of Biochemistry 	Hypogonadism in men with type 2 Diabetes- Effect of Letrozole : A randomized controlled trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. DCGI permission needs to be obtained 2. Clarify regarding the level of risk as minimal risk 3. ICF- Part II – delete “storage of biological samples for future purpose” 4. Clarify regarding compensation for participation / risks during the study
60.	JIP/IEC/SC/2013/5/442	<p>Investigator: Dr.Milind Machhindra Patil, Senior Resident, Dept. of Endocrinology</p> <p>Guide: Dr.Jayaprakash Sahoo, Assistant professor, Dept. of Endocrinology</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr.Sadishkumar Kamalanathan, 	Effect of metformin on Thyroid function test in patients with subclinical hypothyroidism-A randomized placebo controlled trial	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. DCGI permission needs to be obtained 2. ICF – Clarify regarding compensation for participation/ foreseeable risks/ disability/ death during the study 3. Mention justification for including placebo group 4. ICF- Part II – delete “storage of biological samples for future purpose”

		Associate professor, Dept. of Endocrinology, 2. Dr.A.K.Das, Professor and head of Department, Dept. of Endocrinology, 3. Dr. Sridhar M.G., Professor and head of Department, Dept. of Biochemistry,		
Ophthalmology				
61.	JIP/IEC/2014/1/253	Investigator: Dr. Mukesh Jain, Junior resident, Dept. of Ophthalmology Guide: Dr. K. Ramesh Babu, Associate Professor, Dept. of Ophthalmology Co-Guide: Dr.Renuka Srinivasan, Professor and Head, Dept. of Ophthalmology	“Changes in corneal astigmatism after standard temporal incision phacoemulsification versus corneal topography guided incision phacoemulsification-a randomized control trial”	Accepted with the following corrections: 1.ICF- Clarify on the level of risk, expected risk and unforeseeable risk.
Radiotherapy				
62.	JIP/IEC/2014/1/254	Investigator: Dr. Bharadhwaj K., Junior Resident, Dept. Of Radiotherapy Guide: Dr. Shyama Prem S., Associate Professor, Department Of Radiotherapy Co-Guide: Dr. Vivekanandam S., Professor & Head, Dept. of Radiotherapy Dr. Jagadesan P., Assistant Professor, Dept. of Radiotherapy Mr. Seenisamy R., Lecturer in Medical Physics, Dept. of Radiotherapy	Comparison of dosimetric param of volumetric modulated arc ther (vmat) & 3d conformal radiothe (3dcrt) in post mastectomy patie with carcinoma breast	Accepted with the following corrections: 1.Change the number of study group to one in the proto 2.Informed consent to be taken after explaining both procedures of the study.
63.	JIP/IEC/2014/1/255	Investigator: Dr.Abhishek Raghava K S, Junior Resident, Dept. Of Radiotherapy Guide: : Dr. V.Parthasarathy, Associate Professor, Dept. Of Radiotherapy Co-Guide: 1. Dr. S.Vivekanandam, Professor & Head, Dept. Of Radiotherapy 2. Mr. K. Saravanan, Lecturer In Radiology (Medical Physics), Dept. Of	Effect of high dose rate brachytherapy boost before external beam radiotherapy on clinical outcomes and toxicity assessment in oral cavity cancers – a preliminary study	Accepted with the following corrections: 1. Clarify the expected risks and compensation for unforeseeable risks.

		Radiotherapy		
Orthopaedics				
64.	JIP/IEC/2014/1/256	Investigator: Dr. Senthilkumar, JR, Dept. of Orthopedics Guide / Co-Guide: 1. Dr. Murali Poduval, Additional Professor, Dept. of Orthopaedics 2. Dr. Jagdish Menon, Professor & HOD, Dept. of Orthopaedics	Short term functional and Radiological outcome of total Hip replacement in inflammatory arthritis patients	Accepted with the following corrections: 1. Revise the study protocol regarding methodology and level of risk in 2.ICF as suggested by IEC (Explain clearly that it is only observational study).
65.	JIP/IEC/2014/1/257	Investigator: Dr. Udit Kumar Biswal, Junior resident, Department of orthopaedics Guide / Co-Guide: 1. Dr. Nataraj. A.R, Associate professor, Dept. of Orthopaedics 2. Dr. Murali Poduval, Additional professor, Dept. of Orthopaedics 3. Dr. Gopisankar @ Balaji G., Assistant Professor, Dept. of Orthopaedics	Comparative evaluation of arthroscopically assisted anterior cruciate ligament reconstruction using patellar tendon and hamstring autografts: a randomized study	Accepted with the following corrections: 1. Clarify on expected and unforeseeable risks to the patient 2. Clarify on compensation for expected and unforeseeable risks
66.	JIP/IEC/2014/1/258	Investigator: Dr. Prasanna T Y, JR, Dept. of Orthopedics Guide / Co-Guide: 1. Dr. Jagdish Menon, Professor And Hod, Dept. Of Orthopedics 2. Dr. Nataraj A R, Associate Professor, Dept Orthopedics 3. Dr. Dhanapathi Halanaik, Associate Professor, Dept. Of Nuclear Medicine	Clinico-radiological outcome of Radio-synovectomy using P-32 Samarium in patients with Chronic Knee Synovitis.	Accepted with the following corrections: 1. Change level of risk to "more than minimal risk" 2. Clarify on expected and unforeseeable risks to the patient in ICF 3. Clarify on compensation for expected, unforeseeable risks and death 4. Resubmit with all investigators signatures
Obst. & Gynaecology				
67.	JIP/IEC/2014/1/259	Investigator: Dr. Nasreen Fatima, Junior Resident, Dept. of Obst. & Gynae Guide: Dr. Latha chaturvedula, Professor, Dept. of Obst. & Gynae Co-Guide: Dr. Syed Habeebullah, Professor, Dept. of Obst. & Gynae	Evaluation of infertility by hysterolaparoscopy	Accepted with the following corrections: 1. Change the duration of study from 2013 to after getting IEC approval 2. Change level of risk to "minimal risk"
68.	JIP/IEC/2014/1/260	Investigator: Dr. Priyanka Sinha, Junior resident, Dept. of	Effect of Laparoscopic Ovarian Drilling on Clinical and	Accepted with the following corrections: 1. Change the duration of study from 2013 to after

		Obstetrics & Gynaecology, Guide: Dr. T. Chitra, Assistant Professor, Dept.of Obstetrics & Gynaecology, Co-Guide: 1. Dr. Dasari Papa, Professor, Dept.of Obstetrics & Gynaecology, 2. Dr. H.Nandeesh, Assistant Professor, Dept. of Biochemistry	Hormonal Profile in Clomiphene Citrate resistant Infertile Women with Polycystic Ovary Syndrome	getting IEC approval
Urology				
69.	JIP/IEC/2014/1/261	Investigator: Dr.Manoj Kumar Das, Senior Resident, Dept. of Urology Guide: Dr. Manikandan R. Assistant professor Dept. of Urology. Co-Guide: 1. Dr.Sandeep Kumar Mishra, Assistant professor, Dept. of Anesthesiology 2. Dr.Santoshkumar, Professor, Dept. of Urology 3. Dr.L.N. Dorairajan, Professor and Head, Dept. of Urology 4. Dr.Muruganandham K., Assistant professor, Dept. of urology	“To compare the efficacy of ultrasound guided intercostal nerve block with nephrostomy tract infiltration of local anesthetic agent after percutaneous nephrolithotomy: A randomized study”	Accepted with the following corrections: 1.Change the duration of study from 2013 to after getting IEC approval 2.Include assent form for children 15 yrs to < 18 yrs in addition to consent from parents / LAR 3.Clarify on compensation for expected, unforeseeable risks and death
70.	JIP/IEC/2014/1/262	Investigator: Sandhya Pandey, SR, Dept. of Plastic Surgery Guide: Dr.Ravi Kumar Chittoria, HOD, Dept. of Plastic Srugery Co-Guide: Dr.D.M.Thappa, Professor, Dept. of Drmatology & STD Dr.Friji M T, Associate Professor, Dept. of Plastic Srugery Dr. Dr.Dinesh	To Compare therapeutic efficacy of combination of intralesional triamcinolone acetonide with 5-fluorouracil versus triamcinolone acetonide alone in treatment of keloid	Accepted with the following corrections: 1. DCGI approval needed 2. Include assent form for children 15 yrs to < 18 yrs in addition to consent from parents / LAR 3. Clarify on compensation for participation, expected, unforeseeable risks and death 4. Clarify on level of risk as “Minimal risk”
71.	JIP/IEC/2014/1/263	Investigator: Bibilash BS, Senior Resident, Department of Plastic Surgery	“Efficacy of Nd:YAG Laser in comparison with Intense Pulsed Light (IPL) for	Accepted with the following corrections: 1. Clarify on the expected risks involved in the study 2. Clarify on compensation for participation,

		<p>Guide: Dr. Ravi Kumar Chittoria, Head of the Department, Plastic Surgery</p> <p>Co-Guide</p> <ol style="list-style-type: none"> 1. Dr. DM Thappa Professor, Dept. of Dermatology 2. Dr. Devi Prasad Mohapatra, Assistant Professor, Dept. of Plastic Surgery 3. Dr. Friji MT, Assistant Professor, Dept. of Plastic Surgery 4. Dr. S Dinesh Kumar, Assistant Professor, Dept. of Plastic Surgery 	treatment of Unwanted Body Hair a Randomised Clinical Trial ”	expected, unforeseeable risks and death
Neuro Surgery				
72.	JIP/IEC/2014/1/264	<p>Investigator: Dr Ved Prakash Maurya, MCh Resident, Dept. of Neurosurgery</p> <p>Guide/Co-Guide:</p> <ol style="list-style-type: none"> 1. Venkatesh S Madhugiri, Assistant Professor, Dept. of Neurosurgery 2. Dr. Sunil K Narayan, Senior Professor and Head, Dept. of Neurology, 3. Dr. Vaibhav Wadwekar, Assistant Professor, Dept. of Neurology, 4. Dr. Medha R., Assistant Professor, Dept. of Biochemistry, 5. Dr. Deepak Barathi S, Assistant Professor, Dept. of Radiodiagnosis 	An assessment of the electrophysiologic and metabolic effects of surgical detethering of the spinal cord in patients with tethered cord syndrome - a prospective study	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Clarify on expected risk and unforeseeable risk 2. Clarify regarding the storage of biological sample 3. ICF (Tamil) needs to be revised avoiding medical jargon 4. Level of risk should be mentioned as “more than minimal risk”
Surgical Gastroenterology				
73.	JIP/IEC/2014/1/265	<p>Investigator: Dr. Bhati Gajendra Kumar, M.Ch First year resident, Dept. of surgical gastroenterology</p> <p>Guide / Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Vikram Kate, Professor and Head of the Dept. of Surgical Gastroenterology 2. Dr. Kalayarasan R., Assistant Professor, Dept. of Surgical Gastroenterology 3. Dr. Biju Pottakkat, Assistant Professor, Dept. of Surgical Gastroenterology 4. Dr. Vishnu Prasad NR, Additional 	Correlation of pretherapeutic Neutrophil and Lymphocyte ratio (NLR) and response after neoadjuvant therapy in patients with esophageal cancer	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Change the duration of study from 2013 to after getting IEC approval 2. ICF - Clarify on compensation for unforeseeable risks and death

		<p>Professor Dept. of surgery and Surgical Gastroenterology</p> <p>5. Dr. Rajesh. N. G, Assistant Professor, Dept. of Pathology</p> <p>6. Dr. Shayama Prem S., Assistant Professor, Dept. of Radiotherapy</p>		
74.	JIP/IEC/2014/1/266	<p>Investigator: Dr Gourav Kaushal, M.Ch resident, Dept. of Surgical Gastroenterology.</p> <p>Guide / Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Biju Pottakkat, Assistant Professor, Dept. of Surgical Gastroenterology, JIPMER 2. Dr. Kalayarasan R, Assistant Professor, Dept. of Surgical Gastroenterology, JIPMER 3. Dr. Dhanapathi Halanaik, Assistant Professor, Dept. of Nuclear Medicine 4. Dr. SC Parija, Senior professor in Microbiology and Professor-in-charge & head, Research 	Incidence of biliary communication in patients with liver abscess- a scintigraphic study	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Change the duration of study from 2013 to after getting IEC approval 2. Change the level of risk to more than minimal risk in protocol as well as ICF. 3. Clarify on compensation for participation, expected, unforeseeable risks and death
Nephrology				
75.	JIP/IEC/2014/1/267	<p>Investigator: Dr.Rajesh Kumar Padhi, DM, Dept. of Nephrology</p> <p>Guide : Dr.R.P.Swaminathan, Professor & HOD, Dept. of Nephrology</p> <p>Co-Guide: Dr.Sreejith Parameswaran, Associate Professor, Dept. of Nephrology Dr.P.S.Priyamavada, Assistant Professor, Dept. of Nephrology</p>	Levels of proteinuria in patients with nephrotic syndrome and its association with serum oxidative stress and markers of inflammation	Approved

P&SM				
76.	JIP/IEC/SC/2013/5/456	<p>Investigator: Dr. Divya Nair, Junior Resident, Dept. of P&SM</p> <p>Guide: Dr. Sonali Sarkar, Associate Professor, Dept. of P & SM</p> <p>Co-Guide: Dr. Shivanand Kattimani, Associate Professor, Dept. of Psychiatry</p>	Health status assessment of children aged 6-18 years in children's homes in Puducherry	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Submit proof of approval from Orphanage homes and dept of social welfare 2. In addition to assent, consent should be obtained from LA
Surgical Oncology				
77.	JIP/IEC/2014/1/268	<p>Investigator: Dr. Shanmugasundaram.S, Senior Resident, Dept. of surgical oncology</p> <p>Guide: Dr. Aravind Ramkumar, Associate professor, Dept. of surgical oncology</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. T.S. Ravikumar, Head of Dept., Dept. of surgical oncology 2. Dr. Ravi Kumar Chittoria, Head of Dept., Dept. of Plastic surgery 3. Dr. Dinesh Kumar.S, Associate professor, Dept. of Plastic surgery 4. Dr. Surendrakumar Verma, Professor, Dept. of pathology 	Determinants of the free flaps survival in cancer patients – prospective clinical study	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. Informed consent form both in English and Tamil needs to be submitted.
78.	JIP/IEC/2013/5/201	<p>Investigator: Dr. Niranjana Biswal, Prof, Dept of Pediatrics</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Sitanshu Kar, Asst. Prof, Dept. of PSM 2. Dr. Ashisivam.B, Asst. Prof, Dept. of Pediatrics 3. Mrs. Jane Mary Andrew, PHN, UHC, PSM 4. Dr. Bobby Zacharia, Addl. Prof, Dept. of Biochemistry 5. Dr. S. Mahadevan, Professor, Dept. of Pediatrics 6. Dr. Gautam Roy, Professor & Head, Dept. of PSM 	Role of vitamin D supplementation in prevention of respiratory & enteric infections in urban areas of Puducherry	<p>Accepted with the following corrections:</p> <ol style="list-style-type: none"> 1. ICF – Clarify on compensation for participation 2. Consent to be obtained from parents or LAR
79.	JIP/IEC/2014/1/269	<p>Investigator:</p>	Evaluation of <i>Helicobacter</i>	<p>Accepted with the following corrections:</p>

		<p>Dr. Vikram Kate, Prof, Dept. of Surgery</p> <p>Co-Investigator:</p> <p>1. Dr. Jharna Mandal, Asst. Prof, Dept. of Microbiology</p> <p>2. Dr.S.Suresh Kumar, Asst. Prof, Dept. of Surgery</p>	<p><i>pylori</i> stool antigen immunochromatography test for detection of <i>Helicobacter pylori</i> infection</p>	<p>1. Clarify on the level of risk in protocol and ICF.</p> <p>2. ICF – Clarify on compensation for participation</p> <p>3. Clarify on provision of free treatment for research related injury.</p>
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***: ICF- Informed consent form; LAR – Legally accepted representative**

“Confidentiality of records and participant-identity will not be revealed in publications” – should be included in all proposals to be done in human subjects.

Justice S. Nadamuni Retired District Judge
Chairman,
Institute Ethics Committee
(HUMAN STUDIES)

(Dr. C. Adithan)
Member-Secretary,
Institute Ethics Committee
(HUMAN STUDIES)

To

A) MEMBERS OF INSTITUTE ETHICS COMMITTEE (HUMAN STUDIES)

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3. Dr. K.S. Reddy, Director, Regional Cancer Centre, JIPMER (Member)
4. Dr. Santosh Kumar,– Senior Professor,Dept. of Urology , JIPMER (Member)
5. Dr. C. Adithan, Professor & Head, Department of Clinical Pharmacology, JIPMER (Member Secretary)
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7. Dr. Nandini K. Kumar, Former Deputy Director General Sr. Grade, National Institute of Epidemiology, Chennai. (Member)
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11. Mrs.Vasuki, M.A. M.Phil. Associate Prof.(Retd.) Dept.of Economics, Bharathidasan Govt. Womens College, Puducherry.(Member)
12. Dr. N.Sakthivel, Professor & Head, Department of Biotechnology, Pondicherry University, Kalapet, Puducherry – 605 014.(Member)
13. Ms. Usha, M.L., Advocate, Puducherry (Member)

B) Administrator, JIPMER website

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