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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)  
 Danvantari Nagar, PUDUCHERRY - 605 006

No.DCP/IEC/SC/4/2014

Date:17.04.2014

### **Minutes of Fourth Institute Ethics Sub-Committee (Human Studies)**

**Sub:** Recommendations of the Institute Ethics Sub-Committee (Human Studies) for the year 2014 - Reg.

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The **Fourth Meeting of the Institute Ethics Sub-Committee (Human Studies)** for the year 2014 was conducted on **16.04.2014 (Wednesday)** from **09.30 AM onwards** under the Chairmanship of **Dr.Santosh Kumar, Senior Professor, Department of Urology, JIPMER**. The meeting started with a welcome address by Dr. C. Adithan, member secretary and was attended by Dr. Chandrasekaran (member) and Mrs. M. Vasuki (member). The students and guides of the same were present in the **Dept. of Clinical Pharmacology Seminar Room, III Floor, Institute Block, JIPMER**.

<b>Total No. of Proposals discussed</b>	<b>: 33</b>
<b>No. of Projects approved</b>	<b>: 2</b>
<b>No of Projects approved with minor modifications</b>	<b>: 29</b>
<b>No of Projects recommended to main IEC review</b>	<b>: 2</b>

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to Dr. C. Adithan, Member-Secretary within 10 days. If the revision is satisfactory, the approval certificate will be issued by the Internal Committee of Institute Ethics Sub-Committee (Human Studies). Otherwise, they need to submit 15 copies of proposal (Form 1A) to IEC for its approval. It will be considered as fresh proposal.

The recommendations made by the Sub-committee are given below:

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”.

Sl.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
1.	JIP/IEC/2014/3/280	<p><b>Investigator:</b> Dr Siddharth Sarkar, SR, Dept. of Psychiatry</p> <p><b>Co-Investigator:</b></p> <ol style="list-style-type: none"> <li>1. Dr Sreekanth Sakay, Senior Resident, Dept. of Psychiatry</li> <li>2. Dr Shivanand Kattimani, Associate Professor, Dept. of Psychiatry</li> <li>3. Dr Ravi Philip Rajkumar, Associate Professor, Dept. of Psychiatry</li> </ol>	Prevalence of Catatonia in General Inpatient Psychiatry Services	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Resubmit in the prescribed IEC format (available on JIPMER website).</li> <li>• Provide Tamil translation of all the scales administered in this study.</li> <li>• Mention that confidentiality will be maintained both during study and publication and the records will be preserved for three years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons and without losing any benefits.</li> <li>• Signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> </ul>
2.	JIP/IEC/SC/2014/1/517	<p><b>Investigator:</b> Dr Satyajit Rabha, Resident Mch Neurosurgery course, Dept. of Neurosurgery</p> <p><b>Guide:</b> Dr Roopesh Kumar V R, Additional Professor &amp; HOD, Dept. of Neurosurgery</p> <p><b>Co-Guide:</b> Dr Ramesh AS, Assistant Professor, Dept. of Neurosurgery Dr Sathia Prabhu. A, Assistant Professor, Dept. of Neurosurgery</p>	Atlantoaxial dislocations: current strategies of management - an institutional experience	<p style="text-align: center;"><b>Absent</b></p> <p>Resubmit to IEC Main Committee (15 copies) in the prescribed format.</p>
3.	JIP/IEC/SC/2014/4/558	<p><b>Investigator:</b> <b>Department of Obstetrics and gynecological nursing, College of Nursing</b></p> <ol style="list-style-type: none"> <li>1. Ms. Indumathy. P</li> <li>2. Ms. Priya.Y</li> <li>3. Ms. Reema Alen Babu</li> <li>4. Ms. Syamily G Babu</li> </ol> <p>MSc. Nursing 1<sup>st</sup> Year</p> <p><b>Guide:</b> Mrs. Kanimozhi K, Sister Tutor, Dept. of Obstetrics and Gynecology, College of</p>	Knowledge of staff nurses regarding breast crawl as a method of initiation of breast feeding among the staff nurses working in maternity ward, JIPMER,Puducherry.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention confidentiality will be maintained during study as well as publication and the records will be preserved for three years.</li> <li>• Mention that participant is free to withdraw from the study at any time without assigning any reasons.</li> <li>• Investigator's signature, name and address of</li> </ul>

		<p>Nursing <b>Co-Guide:</b> Mrs. Niksy Abraham, Sister Tutor, Dept. of Obstetrics and Gynecology, College of Nursing</p>		<p>witness needs to be included in ICF.</p> <ul style="list-style-type: none"> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
4.	JIP/IEC/SC/2014/4/559	<p><b>Investigator:</b> Ms.Indumathi.P ,MSc. Nursing 1<sup>st</sup> Year Department of Obstetrics and gynecological nursing, College of Nursing <b>Guide:</b> Mrs. Kanimozhi K, Sister Tutor, Dept. of Obstetrics and Gynecology, College of Nursing <b>Co-Guide:</b> 1. Mrs. Niksy Abraham, Sister Tutor, Dept. of Obstetrics and Gynecology, College of Nursing 2. Dr..Manikandan.K, Associate Professor, Dept. of Obstetrics and Gynecology</p>	<p>Knowledge on hypertensive disorders of pregnancy among pregnant women with hypertensive disorders.</p>	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Investigator's signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
5.	JIP/IEC/SC/2014/4/560	<p><b>Investigator:</b> Ms. Aniciah Marie Kuriakose, M.Sc Nursing Student, College of Nursing <b>Guide:</b> Mrs : Vetriselvi D ,Lecturer, College of Nursing <b>Co-Guide:</b> 1. Mrs.SafeeneBeevi S S ,Sister Tutor, College of Nursing 2. Dr. C. Venkatesh, Assistant Professor, Dept. of Peadiatrics</p>	<p>Incidence of superficial thrombophlebitis and its determinants among hospitalised children receiving intravenous therapy in paediatric wards.</p>	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention level of risk involved.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons and without losing any benefits.</li> <li>• Signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
6.	JIP/IEC/SC/2014/4/561	<p><b>Investigator:</b> Mr.K.Phanendra Kumar, 1<sup>st</sup> year M.Sc. Nursing, College of Nursing <b>Guide:</b> Mrs. Yamuna T.V, Sister Tutor, College of Nursing <b>Co-Guide:</b> Dr.MR.Swaroop Kumar.Sahu, Assistant Professor, Dept. of P&amp;SM</p>	<p>Knowledge and Practice regarding Bio-Medical Waste Management among the Nurses working in JIPMER Hospital Puducherry.</p>	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention that only English ICF is included.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Name and address of witness needs to be included in ICF.</li> </ul>

				<ul style="list-style-type: none"> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Mention free treatment will be provided as per JIPMER guidelines.</li> <li>• Include guide's declaration.</li> </ul>
7.	JIP/IEC/SC/2014/4/562	<p><b>Investigator:</b> Miss. Jisme Mathew, MSc Nursing, 1<sup>st</sup> year, College of Nursing</p> <p><b>Guide:</b> Mrs. Padmavathy Nagarajan, Lecturer, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs Bhuvaneswari, Sister Tutor ,College of Nursing</li> <li>2. Dr. Vikas Menon, Asst Professor, Dept. of Psychiatry</li> </ol>	The effect of psycho education on knowledge, attitude and burden of care givers of clients with bipolar affective disorder.	<p><b>Approved with following modifications:</b></p> <p><b>Referred to Main Ethics Committee for approval. To submit 15 copies incorporating the changes mentioned below:</b></p> <ul style="list-style-type: none"> <li>• Enclose permission from author for using Burden assessment schedule given in appendix A5.</li> <li>• Include guide's declaration.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> </ul>
8.	JIP/IEC/SC/2014/4/563	<p><b>Investigator:</b> Miss. Linsha George, M.Sc Nursing, 1<sup>st</sup> year, College of Nursing</p> <p><b>Guide:</b> Dr.Mrs. Lakshmi.R, Lecturer, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs Arulnisha, Sister Tutor ,College of Nursing</li> <li>2. Dr Santhosh Satheesh, Additional Professor &amp; Head, Dept. of cardiology</li> <li>3. Dr D.K.S Subrahmanyam., Professor, Dept. of Medicine</li> <li>4. Dr Rama Prakasha.S, Assistant Professor, Dept. of Emergency medicine</li> </ol>	Determinants of pre- hospital delay and time to initiation of Reperfusion Therapy among acute ST Segment Elevation Myocardial Infarction(STEMI) patients in JIPMER	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons in Tamil ICF.</li> <li>• Clarify regarding provision of free treatment in Tamil ICF.</li> <li>• Mention that compensation will be provided as per JIPMER guidelines.</li> <li>• Signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
9.	JIP/IEC/SC/2014/4/564	<p><b>Investigator:</b> <b>Medical Surgical Nursing Students, First year, MSc Nursing, College of Nursing</b></p> <ol style="list-style-type: none"> <li>1. Miss.Ancy .M.Das</li> <li>2. Miss.Aneena Dominic</li> <li>3. Miss.Deena Davis</li> <li>4. Miss.Linsha George</li> <li>5. Miss.Sandhya.R.V</li> </ol> <p><b>Guide:</b> Mrs.M,J.Kumari, Vice Principal, College of Nursing</p>	Knowledge regarding common cardiac drugs among staff nurses in cardiac units of JIPMER, Puducherry.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Clarify that the participants are all staff nurses in the main proforma and ICF.</li> <li>• Include signature of investigator in declaration page and add references in the end.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that in proforma that ICF will be given only in English.</li> <li>• Remove the phrase "your treatment will not be affected due to your withdrawal from the study" in ICF-1.</li> </ul>

				<ul style="list-style-type: none"> <li>• Signature, Name and address of witness needs to be included in ICF.</li> <li>• Include guide's declaration.</li> </ul>
10.	JIP/IEC/SC/2014/4/565	<p><b>Investigator:</b> Deena Davis, M.Sc Nursing , First Year, College of Nursing</p> <p><b>Guide:</b> Dr:Mrs Lakshmi R ,Lecturer, College of Nursing,</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs Arul Nisha , Sister Tutor, College of Nursing</li> <li>2. Dr Biju Pottakkat , Assistant Professor, Dept. of Surgical Gastroenterology</li> </ol>	Quality of life of ostomates attending STOMA OPD, JIPMER	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention in electronic data base patient's identity will not be revealed.</li> <li>• Provision of free treatment as per JIPMER guideline.</li> <li>• Clarify regarding compensation for participation in Tamil ICF.</li> <li>• Correct spelling mistakes in Tamil ICF.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Include guide's declaration.</li> </ul>
11.	JIP/IEC/SC/2014/4/566	<p><b>Investigator:</b> Miss. Aneena Dominic, MSc Nursing, 1st year, College of Nursing</p> <p><b>Guide:</b> Mrs.M,J.Kumari, Vice Principal, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs.Angeline Mary Sheela, Sister Tutor ,College of Nursing</li> <li>2. Dr.Suryanarayana B.S, Associate Professor, Dept. of Medicine</li> </ol>	Stratification of risk for diabetic foot ulcer among patients with diabetes mellitus attending diabetic clinic,JIPMER, Puducherry.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page and add references in the end.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention social responsibility of investigator in the ICF.</li> <li>• Provision of free treatment as per JIPMER guideline.</li> <li>• Clarify regarding compensation for participation in Tamil ICF.</li> <li>• Check for concordance between English and Tamil versions of ICF.</li> <li>• Mention benefits to the patient in ICF in Tamil version.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Include the Tamil version of the questionnaire for reference to patients.</li> <li>• Include guide's declaration.</li> </ul>
12.	JIP/IEC/SC/2014/4/567	<p><b>Investigator:</b> Ms. Ancy M Das, 1<sup>st</sup> year MSc Nursing,College of Nursing</p>	Adherence pattern to antiepileptic regimen and its determinants among patients attending the	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include signature of investigator in declaration page.</li> </ul>

		<p><b>Guide:</b> Dr.Mrs. Lakshmi.R, Lecturer, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs.Arul Nisha, Sister Tutor, College of Nursing,</li> <li>2. Dr. Sunil K Narayan, Professor &amp; Head, Dept of Neurology</li> <li>3. Dr. Vaibhav Wadvekar, Associate Professor, Dept. of Neurology</li> </ol>	Neurology OPD, JIPMER, Puducherry.	<ul style="list-style-type: none"> <li>• Exclude patients less than 18 yrs of age.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Investigator's signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
13.	JIP/IEC/SC/2014/4/568	<p><b>Investigator:</b> Ms. Reema Alen Babu, MSc. Nursing 1<sup>st</sup> Year, Dept. of Obstetrics and gynecological nursing, College of Nursing</p> <p><b>Guide:</b> Mrs. Kanimozhi K, Sister Tutor, Department of Obstetrics and Gynecology, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs. Niksy Abraham, Sister Tutor, Dept. of Obstetrics and Gynecology, College of Nursing</li> <li>2. Dr. Anish Keepanasseril, Assistant professor, Dept. of Obstetrics and Gynecology</li> </ol>	Time of initiation of breastfeeding and determinants of early initiation among postnatal mothers admitted in JIPMER, Puducherry.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Exclude pregnant women under 18 yrs of age.</li> <li>• Include signature of investigator in declaration page.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Investigator's signature, Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
14.	JIP/IEC/SC/2014/4/569	<p><b>Investigator:</b> Miss. Sandhya.R.V, MSc Nursing, 1<sup>st</sup> year, College of Nursing</p> <p><b>Guide:</b> Mrs.M.J.Kumari, Vice Principal, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs.Angeline Mary Sheela, Sister Tutor, College of Nursing</li> <li>2. Dr.Gopisankar, Assisstant professor, Dept. of Orthopaedics</li> </ol>	Prevalence of low back pain and knowledge on body mechanics among staff nurses in JIPMER ,Puducherry.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Clarify that the participants are all staff nurses in the main proforma and ICF.</li> <li>• Mention the level of risk involved.</li> <li>• Mention how prevalence of low back pain will be calculated in control population.</li> <li>• Include signature of investigator in declaration page and add references in the end.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that in proforma that ICF will be given only in English.</li> <li>• Remove the phrase "your treatment will not be affected due to your withdrawal from the study" in ICF-1.</li> <li>• Signature, Name and address of witness needs to be included in ICF.</li> </ul>

				<ul style="list-style-type: none"> <li>• Include guide's declaration.</li> </ul>
15.	JIP/IEC/SC/2014/4/570	<p><b>Investigator:</b> Aparna, MSc Nursing 1<sup>st</sup> Year, Child Health Nursing, College Of Nursing</p> <p><b>Guide:</b> Mrs. Vetriselvi D., Lecturer, College of Nursing</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Mrs. Safeena Beevi, Sister Tutor, College of Nursing</li> <li>2. Dr. Ramesh Kumar R, Assistant Professor, Dept. of Paediatrics</li> </ol>	Assessment of knowledge, risk perception and practice of Universal Precautions among Nurses involved in Paediatric care in JIPMER, Puducherry	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Eliminate observation bias during the procedure.</li> <li>• Include signature of investigator in declaration page.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
16.	JIP/IEC/SC/2014/4/571	<p><b>Investigator:</b></p> <ol style="list-style-type: none"> <li>1. Ms. Aniciah Marie Kuriakose</li> <li>2. Ms. Aparna</li> <li>3. Ms. Jayaranjani K.</li> <li>4. Ms. Saranya K.</li> </ol> <p>M.Sc Nursing (Child Health Nursing), College of Nursing</p> <p><b>Guide / Co-Guide:</b> Mrs : Vetriselvi D ,Lecturer,College of Nursing</p>	Assess the knowledge regarding immunization among mothers of under-five children.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include Pediatrician as a medical co-guide.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that study records will be maintained for a period of 3 years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
17.	JIP/IEC/SC/2014/4/572	<p><b>Investigator:</b> Mr. Ritwik Dey, II M.B.B.S Student</p> <p><b>Guide:</b> Dr. Medha R., Associate Professor, Dept. of Biochemistry</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Sreejith Parameswaran, Associate Professor, Dept. of Nephrology</li> <li>2. Dr. G.Revathy, Junior Resident, Dept. of Biochemistry</li> </ol>	Association of magnesium status with lipid alterations in patients with chronic kidney disease.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Mention regarding maintenance of study records in Tamil ICF.</li> <li>• Include provision of free treatment as per JIPMER guidelines in ICF.</li> <li>• Mention compensation will be provided as per JIPMER guidelines in case of unforeseeable risk, disability or death as per JIPMER guidelines.</li> <li>• Include guide's declaration.</li> </ul>
18.	JIP/IEC/SC/2014/4/573	<p><b>Investigator:</b> Keerthi A.R., 3<sup>rd</sup> Year (VI semester), MBBS</p> <p><b>Guide / Co-Guide:</b> Dr.Sivaraman.G, Assistant Professor, Dept. of Ear, Nose and Throat</p>	Assessment of Otoacoustic Emissions (OAEs) in Mobile Phone Users in a Tertiary Care Teaching Hospital.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Use the term participants for the mobile phone users.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reason.</li> <li>• Mention that free treatment will be given for research related injury in ICF.</li> </ul>

				<ul style="list-style-type: none"> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that study records will be maintained for a period of 3 years.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
19.	JIP/IEC/SC/2014/4/574	<p><b>Investigator:</b> Kadambari.R, R.NO 620, Curie house 2, Hostel complex, JIPMER</p> <p><b>Guide / Co-Guide:</b> Dr.Subashini Kaliaperumal, Associate Professor, Dept. of ophthalmology,</p>	Study of conjunctival microbial flora in intensive care unit patients.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Give investigator's institute address.</li> <li>• Mention how the study will benefit the individual patients.</li> <li>• Clarify regarding the level of risk.</li> <li>• Mention the social responsibilities of the Investigators.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Mention regarding maintenance of study records for three years.</li> <li>• Include provision of free treatment as per JIPMER guidelines in ICF.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include investigator's signature in Tamil ICF.</li> <li>• For minors, consent from parent/LAR to be taken.</li> <li>• For age &gt;7 years, assent form to be included.</li> <li>• Include guide's declaration.</li> </ul>
20.	JIP/IEC/SC/2014/4/575	<p><b>Investigator:</b> Jyotsna Sharma, III yr MBBS</p> <p><b>Guide / Co-Guide:</b> Dr.Gowri Dorairajan, Professor, Dept. of OBG</p>	"Knowledge and attitude towards contraceptive methods of spacing and decision making factors regarding its use in postpartum women"	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Validation of the questionnaire needs to be done before commencing the study.</li> <li>• Mention the benefits to the participants of the study.</li> <li>• Mention the social responsibilities of the Investigators.</li> <li>• If women less than 18 years of age recruited, then assent form and consent from parent/LAR needed.</li> </ul>



				<ul style="list-style-type: none"> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Mention regarding maintenance of study records for three years.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
21.	JIP/IEC/SC/2014/4/576	<p><b>Investigator:</b> Anuradha Maji , II year MBBS</p> <p><b>Guide:</b> Dr. R. Raveendran, Professor, Dept. of Pharmacology</p> <p><b>Co-Guide:</b> Dr.Chanaveerappa Bammigatti, Associate Professor, Dept. of Medicine</p>	Effect of beta-blockers on glycosylated hemoglobin (HbA <sub>1c</sub> ) levels in non-diabetic subjects.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Clarify regarding the amount of blood sample which will be drawn from the study subjects.</li> <li>• Mention confidentiality will be maintained both during study and publication and the information will be shared without revealing identity.</li> <li>• Mention that the records will be kept for a period of three years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reason, delete the word "valid".</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
22.	JIP/IEC/SC/2014/4/577	<p><b>Investigator:</b> Snehasis Smrutiranjana Das, 2<sup>ND</sup> YEAR MBBS Student, JIPMER</p> <p><b>Guide:</b> Dr. S.Sandhiya, Assistant Professor, Dept. of Clinical Pharmacology,</p> <p><b>Co-Guide:</b> Dr. Ravi Philip Rajkumar, Associate Professor, Dept. Of Psychiatry</p>	Occurrence of adverse drug reactions with antipsychotic drugs among patients attending the psychiatry OPD in tertiary care hospital	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Mention how the study will benefit the individual patients.</li> <li>• Mention the social responsibilities of the Investigators.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention regarding maintenance of study records for three years.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
23.	JIP/IEC/SC/2014/4/578	<p><b>Investigator:</b> Anusha Narayanan, III year M.B.B.S</p> <p><b>Guide / Co-Guide:</b> Dr. Smita Kayal, Assistant Professor, Dept. of Medical Oncology</p>	Pattern of electrolyte abnormalities in patients receiving platinum based chemotherapy	<b>Approved and Waiver for taking consent granted.</b>

24.	JIP/IEC/SC/2014/4/579	<p><b>Investigator:</b> Nivya Mathew, III year MBBS</p> <p><b>Guide / Co-Guide:</b> Dr. Vishnu Bhat, Senior Professor &amp; Head, Dept. of Paediatrics</p>	Clinical profile and outcome of Serratia infection among neonates.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Mention that it is a prospective cohort study.</li> <li>• Signature of investigator to be included in declaration page.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Mention regarding maintenance of study records for three years.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
25.	JIP/IEC/SC/2014/4/580	<p><b>Investigator:</b> R.Ragasudha, MBBS, III year</p> <p><b>Guide / Co-Guide:</b> Dr.Krishna Kumar.G, Assistant professor, Dept. of Pediatric Surgery</p>	Use of Pain Assessment Tool (PAT) score in the assessment of pain neonates	<p><b>Approved with following modifications</b></p> <ul style="list-style-type: none"> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that records will be preserved for three years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Avoid repetition in ICF (Item no. 11 and 15).</li> <li>• Include assent form from children &gt;7 years of age and informed consent from parent/LAR.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration</li> </ul>
26.	JIP/IEC/SC/2014/4/581	<p><b>Investigator:</b> Sumana.K.A, 3<sup>rd</sup> MBBS</p> <p><b>Guide / Co-Guide:</b> Dr.Nirupama Kasturi, Assistant Professor, Dept. of Ophthalmology</p>	Prevalence of red-green colour blindness among children above 5 years of age attending Paediatric Out-Patient Department, JIPMER	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Mention how the study will benefit the individual patients.</li> <li>• Mention the social responsibilities of the Investigators.</li> <li>• Clarify regarding level of risk.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Include provision of free treatment as per JIPMER guidelines in ICF in Tamil version.</li> <li>• Name, signature and address of witness needs</li> </ul>

				<p>to be included in ICF.</p> <ul style="list-style-type: none"> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration.</li> </ul>
27.	JIP/IEC/SC/2014/4/582	<p><b>Investigator:</b> Saranya .R, No. 31, 1<sup>st</sup> floor, 100ft road, Sundarajan Nagar, Mudaliarpet</p> <p><b>Guide / Co-Guide:</b> Dr. Venkatesh Chandrasekaran, Assistant Professor, Dept. of Pediatrics</p>	Maternal and birth risk factors for children screening positive for autism spectrum disorders on M-CHAT-R.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Give investigator's institute address.</li> <li>• Names of co guides need to be included in the proforma.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Include assent form for participants less than 18 years of age in addition to informed consent from parent/LAR.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Name and address of witness needs to be included in ICF.</li> <li>• Include guide's declaration.</li> </ul>
28.	JIP/IEC/SC/2014/4/583	<p><b>Investigator:</b> Praveen. J, No 47. LIG D block, Suthantheta ponvizha nagar, Puducherry 605 011 .</p> <p><b>Guide / Co-Guide:</b> Dr. Siddaraju, Professor, Dept. of Pathology</p>	Significance of mast cells in the diagnosis and grading of nodal Non-Hodgkins lymphoma(NHL) on Fine Needle Aspiration Cytology(FNAC)	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Give investigator's institute address.</li> <li>• Include guide's declaration.</li> <li>• Patient's identity will not be revealed during publication.</li> </ul>
29.	JIP/IEC/SC/2014/4/584	<p><b>Investigator:</b> Angeline Mary.S, No.22, Montorsier St, Pondicherry</p> <p><b>Guide / Co-Guide:</b> Dr.Bikash Kumar Naredi, Assistant Professor, Dept. of Paediatric Surgery.</p>	Uroflowmetry Nomogram for healthy South Indian Children aged between 3-12 years of age	<p><b>Approved with following modifications</b></p> <ul style="list-style-type: none"> <li>• Give investigator's institute address</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention that records will be preserved for three years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Avoid repetition in ICF (Item no. 11 and 15).</li> <li>• Include assent form from children &gt;7 years of age and informed consent from parent/LAR.</li> <li>• Name, signature and address of witness needs to be included in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide's declaration</li> </ul>
30.	JIP/IEC/SC/2014/4/585	<p><b>Investigator:</b> Hrishikesh Dadhich II MBBS Student</p> <p><b>Guide / Co-Guide:</b> Dr Pampa Ch Toi, Associate Professor, Dept.</p>	A Comparison between Conventional Cytopreparatory and Liquid Based Cytological Techniques in evaluation of Serous Effusion Fluids.	<p><b>Approved:</b></p> <ul style="list-style-type: none"> <li>• Waiver of consent granted.</li> </ul>

		of Pathology		
31.	JIP/IEC/SC/2014/4/586	<p><b>Investigator:</b> Kunal Pradip Kanakia, MBBS Undergraduate student, 2<sup>nd</sup> year</p> <p><b>Guide / Co-Guide:</b> Dr C Palanivel, Assistant Professor, Dept. of Preventive and Social Medicine</p>	Tobacco use among presumptive tuberculosis patients attending designated microscopy centre in a tertiary care centre.	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention study records will be maintained for 3 years.</li> <li>• Include a structured questionnaire for assessing education status.</li> <li>• Use the terms “participants” uniformly throughout the study.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Remove clause regarding storage of samples.</li> <li>• Include name of the witness.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide’s declaration.</li> </ul>
32.	JIP/IEC/SC/2014/4/587	<p><b>Investigator:</b> Sonia Agrawal, Curie house 2, JIPMER, Puducherry.</p> <p><b>Guide / Co-Guide:</b> Dr. Subitha L., Asst Prof, Community Medicine</p>	Doctor shopping and health-care seeking behavior among diabetic patients in a selected urban area of Puducherry	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Include Investigator’s JIPMER address.</li> <li>• Clarify regarding the duration of the study.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention study records will be maintained for 3 years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Include assent form from children &gt;7 years of age and informed consent from parent/LAR.</li> <li>• Include name and address of the witness in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide’s declaration.</li> </ul>
33.	JIP/IEC/SC/2014/4/588	<p><b>Investigator:</b> Ms. Sunandha.T, MSc Nursing, 1st year, College of Nursing</p> <p><b>Guide:</b> Dr.Revathi, Principal, College of Nursing</p> <p><b>Co-Guide:</b> Dr. Subitha L., Asst Prof, Community Medicine</p>	A study to assess the knowledge, perception of risk factors and barriers towards cervical cancer screening among women residing in villages under JIRHC, Puducherry	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Clarify regarding the duration of the study.</li> <li>• Mention confidentiality will be maintained both during study and publication.</li> <li>• Mention study records will be maintained for 3 years.</li> <li>• Mention that participant can withdraw from the study at any time without assigning any reasons.</li> <li>• Include name and address of the witness in ICF.</li> <li>• Concordant changes to be made in Tamil ICF.</li> <li>• Include guide’s declaration.</li> </ul>

ICF – Informed consent form; LAR –legally acceptable representative

(Dr.Santosh Kumar)  
Chairman  
Institute Ethics Sub Committee  
(HUMAN STUDIES)  
Senior Professor of Urology

(Dr. C. Adithan)  
Member Secretary  
Institute Ethics Committee  
(HUMAN STUDIES)  
Senior Professor & HOD of Clinical Pharmacology

**To**

- |  |                           |
|--|---------------------------|
| <b>1. Dr.Santosh Kumar, Senior Professor, Department of Urology, JIPMER</b>                      | <b>(Chairman)</b>         |
| <b>2. Dr.C.Adithan, Senior Professor &amp; Head, Department of Clinical Pharmacology, JIPMER</b> | <b>(Member Secretary)</b> |
| <b>3. Dr.M.G.Sridhar, Senior Professor &amp; Head, Department of Biochemistry, JIPMER</b>        | <b>(Member)</b>           |
| <b>4. Dr.K.Chandrasekaran, Associate Professor, Dr.Ambedkar Govt. Law College, Pondicherry</b>   | <b>(Member)</b>           |
| <b>5. Mrs.M.Vasuki, Muthialpet, Pondicherry</b>  | <b>(Member)</b>           |

**Copy to :**

PS to Director / Medical Superintendent / Dean / Chairman, Institute Ethics Committee (Human Studies) for information.