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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/2/2014

Date:12.02.2014

**Minutes**

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

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The **Second Meeting of the Institute Ethics Sub-Committee (Human Studies) for the year 2014** to review the proposals submitted on or before 10.01.2014 was conducted on **12.02.2014 (Wednesday) from 2.30 PM onwards** under the Chairmanship of **Dr.Santosh Kumar, Senior Professor, Department of Urology, JIPMER**. The students and guides of the same were present in the **Dept. of Clinical Pharmacology Seminar Room, III Floor, Institute Block, JIPMER**.

**Total No. of Proposals discussed:47**

**No. of New Proposals discussed: 6**

**No of revised proposal from subcommittee:39**

**No of revised proposal from main committee:2**

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.

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

**All Investigators are required to give the following declaration, to be included as point 13 of the format.**

- a) All procedures to be used on participants are professionally acceptable.**
- b) All procedures to be used on participants are standardized.**
- c) All adverse events during the study will be recorded.**

SI.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
1.	JIP/IEC/SC/2014/2/546	<p><b>Investigator:</b> Ms.Ramya M, Ph.D Scholar, Dept. of Pathology</p> <p><b>Guide:</b> Dr. Surendra Kumar Verma, Professor, Dept. of Pathology</p> <p><b>Co- Guide:</b> Dr. Venkatesh S Madhugiri, Associate Professor, Dept. of Neuro Surgery</p>	Expression of leptin and its receptors in Oligo-Astrocytic Neoplasma	<p><b>Approved with following corrections:</b></p> <ul style="list-style-type: none"> <li>Part of the previously approved project No. JIP/IEC/2014/1/212 for which corrections suggested by main committee have been carried out <b>except</b>, copy of NIMHANS approval letter to be submitted as per main committee minutes dated 29-1-14.</li> <li>ICF-2-Name and address of witness needs to be added.</li> <li>ICF (English) freedom to withdraw without assigning any reason has to be added</li> <li>Assent needs to be obtained from children above 7 years of age, in addition to consent form from parents/LAR.</li> <li>NIMHANS samples should be obtained in decoded format.</li> </ul>
2.	JIP/IEC/SC/2014/2/547	<p><b>Investigator:</b> Dr.Veera Bhadra R., SR, Dept. of Pediatric Surgery</p> <p><b>Guide:</b> Dr.Kumaravel S., Associate Professor, Dept. of Paediatric Surgery</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>Dr.Bibekanand Jindal, Associate Professor, Dept. of Paediatric Surgery</li> <li>Dr.Krishna Kumar, Assistant Professor, Dept. of Paediatric Surgery</li> <li>Dr.Bikash Kumar Naredi, Assistant Professor, Dept. of Paediatric Surgery</li> <li>Dr.Priyamvada P.S, Assistant Professor, Dept. of Nephrology</li> <li>Dr.H.Nandeeshha, Assistant Professor, Dept. of Biochemistry</li> </ol>	Clinico-Biochemical profile of children with congenital anomalies of kidney and urinary tract (CAKUT) with special emphasis on hypertensive.	<p><b>Approved with following corrections:</b></p> <ul style="list-style-type: none"> <li>Justification for sample size needs to be included</li> <li>ICF (English) freedom to withdraw without assigning any reason has to be added</li> <li>ICF (Tamil) – freedom to withdraw child needs to be changed similar to English version</li> <li>Name and address of witness needs to be added</li> <li>Mention children below 18 yrs will be included under inclusion criteria</li> <li>Assent needs to be obtained from children above 7 yrs of age in addition to consent from parents / LAR</li> <li>Signature of the investigator in the declaration page needs to be added</li> </ul>

				<ul style="list-style-type: none"> <li>Confidentiality during participation, preservation of records and publication needs to be added</li> <li>Storage of sample needs to be clarified</li> <li>Name and address of witness needs to be added</li> </ul>
3.	JIP/IEC/SC/2013/5/465	<p><b>Investigator:</b> Karthik.P, SR, Dept. of CTVS</p> <p><b>Guide:</b> Dr. Ram Sankar, Assistant Professor, Dept. of CTVS</p> <p><b>Co-Guide:</b> Dr. Sai Chandran, HOD, Dept. of CTVS.</p>	Short term outcome of fenestrated or unidirectional valved patches for repair of cardiac septal defects in patients with severe pulmonary arterial hypertension	<ul style="list-style-type: none"> <li>Mention that all procedures used in this study are standard of care and professionally acceptable</li> <li>Protocol format incorrect, please resubmit in the JIPMER IEC IB format which can be downloaded from JIPMER website.</li> <li>Tamil ICF – to be included</li> <li>Compensation for foreseeable and unforeseeable risk as per JIPMER guideline needs to be added</li> <li>Revised protocol needs to be resubmitted in the JIPMER IEC format (15 copies) to main committee IEC meeting to be held on 28-2-14</li> </ul>
4.	JIP/IEC/SC/2014/1/487	<p><b>Investigator:</b> Dr.Vishal Kumar Chitikeshi, 1 year Junior Resident, Dept. of Pulmonary medicine,</p> <p><b>Guide:</b> Dr.S.Vinod Kumar, Professor and Head, Dept. of Pulmonary Medicine</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>Dr.R.Manju, Assistant Professor, Dept. of Pulmonary medicine,</li> <li>Dr.Jyoti Wadhwa, Assistant professor, Dept. of Medicine,</li> </ol>	A study of prevalence of Osteoporosis in patients with chronic obstructive pulmonary disease: a hospital based cross sectional study	<p><b>Approved with following corrections:</b></p> <ul style="list-style-type: none"> <li>Mention that all procedures used in this study are standard of care and professionally acceptable</li> <li>Title to be included in the signature page</li> <li>Expected duration of participants needs to be clarified</li> <li>Risks expected from study to participants needs to be mentioned</li> <li>Justify inclusion of healthy controls in the study</li> <li>List of investigations done in healthy controls needs to be submitted</li> <li>Radiography of chest, thoracic and lumbar spine is not allowed</li> </ul>

				<p>for control group</p> <ul style="list-style-type: none"> <li>• ICF- should be separate for patients and healthy controls</li> <li>• Confidentiality during participation, preservation of records and publication needs to be added</li> <li>• Compensation for foreseeable and unforeseeable risk as per JIPMER guideline needs to be added</li> <li>• Delete the clause regarding storage of biological samples in ICF-2 in English and Tamil version.</li> <li>• ICF (English) needs to be in line with ICF(Tamil)</li> <li>• Name and address of witness needs to be added</li> </ul>
5.	JIP/IEC/SC/2014/1/488	<p><b>Investigator:</b> Dr. Balla Naga Malli Kumar, Junior Resident, Dept. of Pulmonary Medicine</p> <p><b>Guide:</b> Dr. S. Vinod Kumar, Professor And Head, Department Of Pulmonary Medicine</p> <p><b>Co-Guide:</b></p> <ol style="list-style-type: none"> <li>1. Dr. S.Sujatha, Professor, Department Of Microbiology</li> <li>2. Dr. Suryanarayana. Bs, Associate Professor, Department Of Medicine</li> <li>3. Dr. R.Manju, Assistant Professor, Department Of Pulmonary Medicine</li> </ol>	Comparison of clinical, radiological and bacteriological patterns between the community acquired pneumonia patients with and without type 2 diabetes mellitus	<p><b>Approved with following corrections:</b></p> <ul style="list-style-type: none"> <li>• Mention that all procedures used in this study are standard of care and professionally acceptable</li> <li>• Assent needs to be obtained from children above 7 yrs of age in addition to consent from parents / LAR</li> <li>• Delete the clause regarding storage of biological samples in ICF-2 in English and Tamil version.</li> <li>• ICF-1 (Tamil) – change level of risk as given in English ICF</li> <li>• ICF (Tamil) – freedom to withdraw child needs to be changed similar to English version</li> <li>• Signature of the investigator in the declaration page needs to be added</li> <li>• Confidentiality during participation, preservation of records and publication needs to</li> </ul>

				<p>be added</p> <ul style="list-style-type: none"> <li>• Compensation for foreseeable and unforeseeable risks, disability and death as per JIPMER guideline needs to be added</li> <li>• Mention for research related injury free treatment will be provided as per JIPMER guidelines.</li> <li>• Name and address of witness needs to be added</li> </ul>
6.	JIP/IEC/SC/2014/1/489	<p>Investigator: Dr. Harshit, Junior resident, Department of Radio-diagnosis</p> <p>Guide: Dr. Deepak Barathi S, Assistant Professor, Department of Radio diagnosis</p> <p>Co-Guide: 1. Dr. S Elangovan, Professor, Department of Radio diagnosis 2. Dr. L Dorairajan, Professor, Department of Urology</p> <p>Dr Bhavana Badhe, Professor, Department of Pathology</p>	<p>The diagnostic accuracy of diffusion weighted magnetic resonance imaging with apparent diffusion coefficient values in the characterisation of renal masses</p>	<p><b>Approved with following corrections:</b></p> <ul style="list-style-type: none"> <li>• Mention that all procedures used in this study are standard of care and professionally acceptable</li> <li>• Mention added benefits to patients due to MRI</li> <li>• Justify sample size</li> <li>• ICF-“Compensation will not be given for participation”-needs to be added.</li> <li>• ICF- Compensation for foreseeable, unforeseeable risk, disability and death as per JIPMER guideline needs to be added</li> <li>• ICF-Study related injury will be treated free of cost as per JIPMER guidelines.</li> <li>• ICF Q13 missing-needs to be added</li> <li>• Level of risk needs to be clarified</li> <li>• MRI has to be done free of cost to patients involved in this study.</li> <li>• ICF 2 Signature of Investigator missing</li> <li>• ICF Tamil and English need to be concordant</li> <li>• Mention freedom to withdraw without assigning any reason to be mentioned in ICF-Tamil version.</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**

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

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