

\*9Grams: "JIPMER"  
Telex : 0469 -244-JIP IN  
Website: www.jipmer.edu



Phone: 2272380 to 2272390  
Fax : 0413 - 2272067  
2272735, 2272066

**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/5/2014

Date:05. 06. 2014

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

The **Fifth Meeting of the Institute Ethics Sub-Committee (Human Studies) for the year 2014** to review the proposals submitted was conducted on 05.06.2014 (Thursday) at 10.00 AM onwards under the Chairmanship of Dr.Santosh Kumar, Senior Professor, Department of Urology, JIPMER. The meeting was attended by Dr. C. Adithan, Member Secretary, IEC, sub committee and members of IEC sub committee Dr. M.G. Sridhar, Prof and Head, Dept of Biochemistry, Dr. Chandrasekaran, Associate Professor, Dr.Ambedkar Govt. Law College and Mrs. M. Vasuki, Muthialpet, Pondicherry.

<b>Total No. of Proposals discussed</b>	<b>: 7</b>
<b>No. of Projects approved</b>	<b>: 0</b>
<b>No of Projects approved with modifications</b>	<b>: 3</b>
<b>No of Projects carried over to main IEC</b>	<b>: 3</b>
<b>No. of Projects for which approval deferred</b>	<b>: 1</b>

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:

Sl.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
1.	JIP/IEC/SC/2014/5/589	<p><b>Investigator:</b> Dr. C Palnivel, Assistant Professor, Dept. of Preventive and Social Medicine</p> <p><b>Co-Investigator:</b> Dr. Gautam Roy, MD, Professor and Head, Dept. of Preventive and Social Medicine</p>	Identification and screening of eligible tuberculosis patients for drug resistance in national tuberculosis programme in Puducherry: An Operational Research.	<p><b>To be resubmitted with following corrections:</b></p> <ul style="list-style-type: none"> <li>• Expand all abbreviations used in protocol.</li> <li>• Procedure needs to be explained in non scientific terms.</li> <li>• Identity of subject should be decoded in the record.</li> <li>• If the subject is found to have TB should be referred to concerned physician.</li> <li>• Permission to be obtained from competent authority.</li> <li>• Statement to include that for patient with MDR TB suitable treatment will be given.</li> <li>• Approved waiver of consent .</li> </ul>
2.	JIP/IEC/SC/2014/5/590	<p><b>Investigator:</b> Mr.Aditya Sengupta, II MBBS Student, JIPMER</p> <p><b>Guide / Co-Guide:</b> Dr. Rajesh N.G, Associate Professor, Department of Pathology</p>	Clinicopathologic study of Panniculitis in Skin biopsy	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• Correct discrepancies regarding level of risk involved.</li> <li>• Clarify on the storage of biological samples.</li> <li>• Correct all discrepancies between English and Tamil consent forms.</li> <li>• Use uniform term participant to refer to the patient throughout protocol.</li> <li>• Mention confidentiality will be maintained throughout study period and identity will not be revealed during publication.</li> <li>• Mention records will be preserved for 3 years.</li> <li>• Mention that participant can withdraw from the study without assigning any reasons.</li> <li>• Mention age group &gt; 18 yrs will be included in study.</li> </ul>
3.	JIP/IEC/SC/2014/5/591	<p><b>Investigator:</b> Mr. Sripartha Krishna Yerramilli, 3<sup>rd</sup> Year MBBS</p> <p><b>Guide / Co-Guide:</b> Dr. Rakhee Kar, Associate Professor,</p>	Prevalence of fetal hemoglobin containing erythrocytes in circulation of pregnant females using Kleihauer-Betke acid elution method – a hospital based study	<p><b>Approved with following modifications:</b></p> <ul style="list-style-type: none"> <li>• The subject's identify needs to be decoded in the record.</li> <li>• Mention confidentiality will be maintained throughout study period and identity will not be revealed during publication.</li> <li>• If HbF is more, patient should be referred to</li> </ul>

		Department of Pathology		concerned physician. <ul style="list-style-type: none"> <li>• Waiver of consent granted.</li> </ul>
4.	JIP/IEC/SC/2014/5/592	<b>Investigator:</b> Miss.Swati, III MBBS Student, JIPMER, <b>Guide / Co-Guide:</b> Dr.Shashi Ahuja, Associate Professor, Dept. of ophthalmology	Ocular manifestations in HIV patients and its correlation with CD4 count	<b>15 copies to be submitted to main committee.</b>
5.	JIP/IEC/SC/2014/5/593	<b>Investigator:</b> Ms. T. Devika, Ph.D Scholar, Department of Pharmacology <b>Guide / Co-Guide:</b> 1. Dr. D. G. Shewade, Professor, Department of Pharmacology, 2. Dr. D. Biswajit, Associate Professor, Dept. of Medical Oncology	Pharmacogenomics of gemcitabine in patients with metastatic lung cancer.	<b>To be submitted to main committee with following corrections:</b> <ul style="list-style-type: none"> <li>• Compensation will be provided as per JIPMER guidelines.</li> <li>• Confidentiality will be maintained during study and publication.</li> <li>• Records will be preserved for 3 years.</li> <li>• Clarify the clause on storage of biological samples.</li> <li>• Procedure should be explained in simple non medical terms.</li> <li>• Mention that the results of the study have indirect benefit to the future of science and not to the patients directly.</li> <li>• Change the word patients to participants in the protocol.</li> </ul>
6.	JIP/IEC/SC/2013/2/345	<b>Investigator:</b> Dr. D.G.Shewade, Professor, Dept. of Pharmacology <b>Co- Investigator:</b> 1. Dr. Biswajit Dubashi, Asst.Professor, Dept. of Medical oncology, 2. Mr.S.Gopinath.S, Ph.D scholar, Dept. of pharmacology	Effect of ABCB1, GST, CYP2B6 and CYP2C19 gene polymorphism on pharmacokinetics and outcome in breast cancer patients receiving anthracycline based regimens	<ul style="list-style-type: none"> <li>• <b>To get approval from JIPMER scientific committee and resubmit to main IEC.</b></li> <li>• <b>Mention in the covering letter that the study is a part of already approved project.</b></li> </ul>

7.	JIP/IEC/SC/2014/5/594	<b>Investigator:</b> Deeparaj L., I yr MBBS Student, JIPMER. <b>Guide / Co-Guide:</b> Gopalakrishnan M.S, Associate Professor, Dept. of Nerurology.	Utility of bleed to brain ratio in CT scans of head trauma patients for predicting the need for operation and patient outcome.	<b>Since the proposal is not approved by UG scientific committee the decision is deferred.</b>
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For student projects, the guide should give a signed statement on a separate sheet with details of project proposal that “I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me”.

(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, Senior Professor & Head, Department 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.