

JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH, PUDUCHERRY-605006
(Institute of National Importance under Govt. of India)

INSTITUTE ETHICS COMMITTEE (HUMAN STUDIES), JIPMER, PUDUCHERRY- 6.

Date: 24/02/2015

CIRCULAR

Minutes of Fourteenth Meeting of Institute Ethics Sub-Committee (Human Studies)

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Fourteenth Meeting of the Institute Ethics Sub-Committee (Human Studies) was held on 23-02-2015 in the Institute Ethics Committee Room (No. 101), 1st Floor, Administrative Block, JIPMER, under the chairmanship of Dr. Santosh Kumar, Senior Professor, Department of Urology.

The agenda was:-

1. Consideration for approval of the following Research Projects

After deliberation the following decisions were arrived at

- Number of proposals approved : 3
- Number of proposals approved subject to corrections : 6
- Number of proposals recommended to full IEC : 1
- Total number of proposals discussed : 10

Instructions to be followed during submission of proposals:

The investigators whose proposals need modifications are required to send one copy of revised proposal along with CD and a copy of original proposal to Dr. T.K. Dutta, Member-Secretary on or before 06-03-2015 at Institute Ethics Committee room (Room No: 101, opposite to DDA's room, 1st floor, Administrative Block) between 3.30 – 4.30 pm from Monday to Friday. Please follow the IEC format as given in the JIPMER website in the revised protocols and highlight the changes with a yellow highlighter. Kindly submit corrected protocol with both English and Tamil consent forms stapled together. Protocols and consent forms submitted separately will not be considered for approval process. In addition, the candidates need to submit a covering letter enumerating the comments from the IEC minutes for their proposal, with point to point mention of where the revision has been highlighted.

If the revision is satisfactory, the approval certificate will be issued after consulting the subcommittee. Otherwise, they need to submit 15 copies of proposal (Form 1A) to IEC for its approval and it will be considered as fresh proposal.

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

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

Sl. No.	Re. No.	Names of Investigators and Co-investigators	Title of the Research Projects	Recommendations
1	JIP/IEC/SC/2015/13/726	Investigator: Dr Shahana Gupta, Senior Resident, Surgical Gastroenterology Guide: Dr .Biju Pottakkat, Additional professor and Head, Surgical Gastroenterology	A retrospective study of pathological changes in splenic vein in patients undergoing shunt surgery for EHPVO and NCPF.	Approved subject to following corrections: <ul style="list-style-type: none"> Mention data will be collected and analyzed in de-identified form. Mention confidentiality will be maintained during data collection, analysis, presentation and publication. State that records will be preserved for a period of three years. Waiver of consent granted. Change the level of risk as “Minimal risk”.

2	JIP/IEC/SC/2015/13/727	<p>Investigator: Dr. Gajendra Bhati, M.Ch Resident, Surgical Gastroenterology</p> <p>Co-Investigator: Dr. Kalayrasan R., Assistant Professor, Surgical Gastroenterology</p>	<p>Thoracoscopic assisted Esophagectomy with Lymphadenectomy along the left recurrent laryngeal nerve following Neoadjuvant chemoradiotherapy for Squamous cell carcinoma of the esophagus: Feasibility and significance.</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention data will be collected and analyzed in de-identified form. (Name, Hospital no, address and date of admission of patient needs to be removed) • Clarify duration of study in the protocol. • Mention confidentiality will be maintained during data collection, analysis, presentation and publication. • State that records will be preserved for a period of three years. • Waiver of consent granted. • Change the level of risk as "Minimal risk".
3	JIP/IEC/SC/2015/13/728	<p>Investigator: Dr. Gourav Kaushal, M.Ch Resident, Surgical Gastroenterology</p>	<p>Annual morbidity, mortality, discharge and operative audit of department of Surgical Gastroenterology.</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention data will be collected and analyzed in de-identified form. (Name, Hospital no, address and date of admission of patient needs to be removed). • Mention confidentiality will be maintained during data collection, analysis, presentation and publication. • State that records will be preserved for a period of three years. • Waiver of consent granted. • Change the level of risk as "Minimal".


				risk . • Use "research" in terms of "audit" in the objective.
4	JIP/IEC/SC/2015/13/729	Investigator: Dr. Donna Mathew, Senior Resident, Neurology Guide: Dr. Sumil.K.Narayan, Professor and Head, Department of Neurology	Cerebrospinal fluid (CSF) phosphorylated Heavy subunit of NeuroFilament (p-NFH) levels and its association with the type and severity of Motor Neuron Disease in South Indian population.	Recommended for IEC full committee.
5	JIP/IEC/SC/2015/13/730	Investigator: Dr. S. Sandhya, Assistant Professor, Clinical Pharmacology Co-Investigator: Dr. R. Manju, Assistant Professor, Pulmonary Medicine Dr. S. Vinod Kumar, Professor, Pulmonary Medicine Dr. C. Sadish Kumar Kamalanathan, Associate Professor, Endocrinology Mrs. N. Revathy, Ph.D Scholar, Pharmacology Dr. C. Adithan, Senior Professor & Head, Clinical Pharmacology	Association of vitamin D level and genetic polymorphism related to vitamin D level on response to inhalation corticosteroids in South Indian patients with persistent asthma. (JSAC and IEC approved proposal submitted for approval of amendments included in the covering letter)	Approved
6	JIP/IEC/SC/2015/13/731	Investigator: Ms. Revathy, Ph.D Scholar, Pharmacology	Influence of genetic polymorphism and prakriti type on response to Inhaled	Approved

7	JIP/IEC/SC/2015/13/732	<p>Guide: Dr. C. Adithan, Senior Professor & Head, Clinical Pharmacology</p> <p>Co-Guide: Dr. S. Vinod Kumar, Professor, Pulmonary Medicine</p> <p>Dr. T. Kathiravan, Assistant professor, Medicine</p> <p>Project Consultant: Dr. Prasanna Lakshmi, Medical Officer, Puducherry State – Indian System of Medicine Department, Puducherry</p>	<p>Corticosteroids (ICS) in South Indian patients with persistent asthma. (JSAC and IEC approved proposal submitted for approval of inclusion of a co-investigator from ayurvedha as given in the covering letter)</p>	
8	JIP/IEC/SC/2015/13/733	<p>Investigator: Mr. Manavalan.M, Final year MBBS</p> <p>Guide: Priyamvada P S, Associate Professor, Nephrology</p>	<p>Association between nutritional status and metabolic acidosis in pre dialysis patients with Chronic Kidney Disease</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention data will be collected and analyzed in de-identified form. • Mention confidentiality will be maintained during data collection, analysis and publication. • Mention records will be preserved for a period of three years. • Mention for research related injury and unforeseen risks treatment will be provided free of cost as per JIPMER guidelines. <p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention data will be collected and

9	JIP/IEC/SC/2015/12/725	<p>Guide: Dr. Raveendranath V, Assistant Professor, Anatomy</p> <p>Co-Guide: Dr. S. Raja, Associate Professor, Cardiology</p>	Resynchronization Therapy In South Indian Population – An Angiographic Study	<p>analyzed in de-identified form.</p> <ul style="list-style-type: none"> • Mention confidentiality will be maintained during data collection, analysis and publication. • Mention records will be preserved for a period of three years. • Waiver of consent granted. • Change the level of risk as Minimal risk.
10	JIP/IEC/SC/2015/12/726	<p>Investigator: Dr. C. Palanivel, Assistant Professor, PSM</p> <p>Co- Investigator: Dr. Gautam Roy, Professor and Head, PSM</p>	Feedback status on treatment initiation of patients diagnosed with tuberculosis in health facilities of Puducherry: A record based study	<p><u>Approved subject to following corrections:</u></p> <ul style="list-style-type: none"> • Waiver of consent granted. • STO permission letter has to be submitted to IEC • Mention confidentiality will be maintained during data collection, analysis, presentation and publication. • Mention records will be preserved for a period of three years. • Change the level of risk as Minimal risk.
10	JIP/IEC/SC/2015/12/726	<p>Investigator: Dr. TS Ravikumar, Director Jawaharlal Institute of Postgraduate Medical Education & Research(JIPMER) Co-Investigator: Dr. K. Murugandham, Co- ordinator, JIPMER Quality</p>	JIPMER QUALITY COUNCIL – A Novel Patient Safety Initiative.	<p>Approved</p>

	Council, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER)	
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Dr. Santosh Kumar
Chairman,
Institute Ethics Sub-Committee (Human Studies)


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

To

A) INSTITUTE ETHICS SUB-COMMITTEE MEMBERS

1.	Dr. Santosh Kumar, Senior Professor, Urology, JIPMER	Chairperson
2.	Dr. T.K. Dutta, Senior Professor, Medicine, JIPMER	Member Secretary
3.	Dr. M.G. Sridhar, Senior Professor, Biochemistry	Member
4.	Dr. S. Sandhiya, Assistant Professor, Clinical Pharmacology	Member
5.	Dr. K. Chandrashekar, Associate Professor, Dr. Ambedkar Govt. Law College, Kalapet	Member
6.	Mrs. M. Vasuki, Puducherry	Member

B) Administrator, JIPMER website

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