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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-3/2014

Date:31.03.2014

Minutes of Third meeting of the Institute Ethics Committee (Human Studies) for the year 2014 held on 27.03.2014

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The Third 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 27.03.2014 (Thursday) at 9.30 AM under the Chairmanship of Shri.S.Nadamuni, District Judge (Retd). The meeting was attended by Dr.Vasantha Muthuswamy (member), Dr. Zile Singh (Member), Dr.Santosh Kumar (Member), Dr. K. Chandrasekaran (Member), Dr.M.G. Sridhar (Member), Mrs. M. Vasuki (Member) and Dr. C. Adithan (Member Secretary) besides the concerned faculty and the post graduate students. The meeting started at 9.30 am with a welcome address by Member Secretary.

In the meeting a total of 14 proposals were discussed. After deliberations the following decisions were arrived at

- Number of proposals approved : 3
- Number of approved subject to minor corrections : 10
- Investigator absent : 1

At the end of meeting, there was discussion among the committee members regarding revision of IEC certificate, informed consent forms and assent forms in accordance with ICMR as well as Schedule Y guidelines. In response, the members gave their suggestions and the modification made in the IEC certificate was approved. It was decided that the suggested changes in ICF will be circulated to IEC members and will be taken for discussion in the next main committee meeting. With this the member secretary thanked all the members and concluded the session.

The investigators whose proposals need minor modifications are required to send three copies of revised proposals and CD to Dr. C. Adithan, Member-Secretary on or before 15-04-2014. 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 and it will be considered as fresh proposal.

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.”

S.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
1.	JIP/IEC/2014/3/277	<p>Investigator: Dr. Madhusudhanan Ponnusamy, Assistant Professor, Dept. of Nuclear Medicine</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Dhanapathi H, Assistant Professor, Dept. of Nuclear Medicine 2. Dr. Nandini Pandit, Additional Professor, Dept. of Nuclear Medicine 3. Mr. Srikanth , Technical Assistant, Dept. of Nuclear Medicine 	Quarter-time acquisition of bone SPECT/CT using 3D reconstruction algorithm and comparison of image quality with full-time acquisition.	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Specify names of Principal & Co-investigators. • Clarify that no funding is needed for the study in the protocol. • Pregnancy test should be done to rule out pregnancy before including women participants with h/o of missed period of more than one week in study. • ICF- delete phrase “I am not pregnant/lactating” for female participants. • Assent form to be attached for children more than 7 years of age. • In ICF, delete the clause “patient will be informed” and replace the phrase “I fully consent” with “I freely consent”. • Clarify regarding preservation of records and freedom to withdraw from the study. • Include name & address of witness in ICF. • Make concordant changes in ICF in English and in Tamil.
2.	JIP/IEC/2014/3/278	<p>Investigator: Dr. Soundravally Rajendiren (PI), Associate Professor, Dept. of Biochemistry</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Pooja Dhiman, Senior Resident , Dept. Of Biochemistry 2. Dr. Veena P: Associate Professor, Dept. of Obstetrics &Gynecology 3. Dr Shivanand Kattimani, Associate Professor, Dept. of Psychaitry 	Association of Vitamin B12 metabolites and related gene polymorphisms with Postpartum Depression.	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Include separate screening consent form for consent to be taken before collecting cord blood. • Mention informed consent will be obtained at the time of recruitment before delivery. • Clarify regarding consent from LAR in Post partum depression group. • Mention when (gestational age in weeks) the pregnancy women will be recruited. • Mention who will assess the neonatal behaviour. • Remove the clause on storage of biological samples in ICF. • Mention the age of pregnant women under inclusion criteria. • Exclude pregnant women <18 yrs of age. • Clarify regarding discrepancy in the level of risk in

				<p>protocol and ICF.</p> <ul style="list-style-type: none"> • Clarify on provision of compensation for participation. • Mention that compensation will be provided for disability and death as per JIPMER guidelines. • Mention that confidentiality of participation will be maintained while sharing the information with co-investigators. • Make concordant changes in Tamil ICF as per English. • Add name and address of witness in ICF-2.
3.	JIP/IEC/2014/3/279	<p>Investigator: Dr. Rashmi Kumari, Assistant professor, Dept. of Dermatology & STD</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. D.M.Thappa, Professor, Dept. of Dermatology & STD 2. Dr. C. Adithan, professor and head, Dept. of Clinical pharmacology 3. Dr. Laxmisha C, Assistant professor, Dept. of Dermatology & STD 	<p>An active-control, Randomized, Prospective, Multicenter, Phase-III comparative clinical study to investigate, efficacy, safety and tolerability of Linezolid 1200mg SR tablet OD when compared with Linezolid 600mg tablet BD in subjects suffering with uncomplicated skin and soft tissue infections.</p>	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Mention the names of collaborating centers. • Mention when randomization will be done. • In the protocol, clarify regarding the sample size to be recruited from JIPMER alone. • Hard copy of signed memorandum of understanding (MoU) with sponsor and Insurance copy has to be submitted to the Ethics Committee, for approval. • In ICF, mention the level of risk. • In ICF, add a clause regarding treatment of adverse effects, if any. • Mention that confidentiality of participation will be maintained while sharing the information with co-investigators and during publication. • Clarify regarding the compensation/payment to be made to the participants of this trial, as per the agreement signed with the pharmaceutical company. • Make concordant changes in Tamil ICF as per English. • Mention confidentiality of the records will be maintained in this study. • Add name and address of witness in ICF.
4.	JIP/IEC/2014/3/280	<p>Investigator: Dr Siddharth Sarkar, SR, Dept. of Psychiatry</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr Sreekanth Sakay, Senior Resident, Dept. of Psychiatry 2. Dr Shivanand Kattimani, Associate Professor, Dept. of Psychiatry 3. Dr Ravi Philip Rajkumar, Associate Professor, 	<p>Prevalence of Catatonia in General Inpatient Psychiatry Services</p>	<p>Absent</p>

		Dept. of Psychiatry		
5.	JIP/IEC/2014/3/281	<p>Investigator: Dr. Sitanshu Sekhar Kar, Associate Professor, Dept. of PSM</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr Gautam Roy, Professor, Dept. of Preventive & Social Medicine 2. Dr. KC Premarajan, Professor, Dept. of Preventive & Social Medicine 3. Dr Sonali Sarkar, Associate Professor, Dept. of Preventive & Social Medicine 4. Dr Ganesh Kumar S, Associate Professor, Dept. of Preventive & Social Medicine 5. Dr Subitha L, Assistant Professor, Dept. of Preventive & Social Medicine 	Implementation of Healthy workplace model in Industrial setting of Puducherry	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Title needs to be changed to be more specific to the objectives, as per the Ethics Committee recommendations. • Specify the work place where the study is proposed to be conducted. • Mention how implementation will be done. • Mention advice regarding referral will be given to participants with high risk. • Delete the line "treatment will not be affected in ICF. • Resubmit to Ethics Committee with all the changes
6.	JIP/IEC/2014/3/282	<p>Investigator: Dr. Rajesh NG, Associate Professor, Department of Pathology</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Bhawana A Badhe, Professor and Head, Dept. of Pathology 2. Dr. Debdatta Basu, Professor, Dept. of Pathology 3. Dr. Biswajith Dubashi, Associate Professor, Dept. of Medical Oncology 4. Dr. Suresh Chandra Pradhan, Professor and Head, Dept. of Pharmacology 	Assessment of Genetic Mutations in Acute Myeloid Leukemia	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Remove the clause "travel allowance for AML patients will be given only for poor patients during follow-up" and clarify regarding compensation for participation and ensure that it is uniform for all participants. • Clarify regarding future uses and storage of biological samples in ICF. • Mention clearly that "blood collection will be done for research purpose and bone marrow aspiration will be done for diagnostic purpose". • Assent form to be attached for children more than 7 years of age
7.	JIP/IEC/2014/3/283	<p>Investigator: Dr. Pooja Dhiman (PI), Senior Resident , Dept. of Biochemistry</p> <p>Co-Investigator: Dr. Soundravally Rajendiren (Co-PI), Associate Professor, Dept. of Biochemistry</p>	"LDL-Cholesterol estimation in Clinical Chemistry - Direct or Indirect?"	<p>Approved</p> <ul style="list-style-type: none"> • Granted waiver for taking informed consent.
8.	JIP/IEC/2014/3/284	<p>Investigator: Dr Kusa Kumar Shaha, Associate Professor, Dept of Forensic Medicine & Toxicology</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr. Ambika Prasad Patra, Senior Resident, Dept. of Forensic Medicine & Toxicology 2. Dr Swaroop Kumar Sahu, Assistant Professor, Dept of Preventive and Social Medicine 	Audit of death certification at JIPMER, Pondicherry	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Waiver for taking informed consent is granted. • Mention audit will be done for a specific duration and not for a specified sample size (698 as mentioned in the study). • Submit MYER method to be followed in the study to IEC. • Mention in the objectives, that awareness will be

				generated among medical fraternity regarding audit of death certification, by publishing this study and its findings.
9.	JIP/IEC/2014/1/245	<p>Investigator: : Dr K. Venkata Anudeep, Junior Resident, Dept. of Medicine</p> <p>Guide: Dr Vinod KV, Associate Professor, Dept. of Medicine.</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 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, Senior Professor, Dept. of Medicine 	“A study of gastric emptying by gastric scintigraphy in patients with type 2 diabetes mellitus and its correlation with symptoms”	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • ICF needs to be separate for diabetic patients and healthy volunteers. • In ICF, risk of radiation exposure should be explained clearly to controls • Compensation given to healthy volunteers needs to be clarified. • Clearly mention that diabetes mellitus patients with co-morbidities will be excluded in the protocol. • Clarify regarding the storage of biological samples. • Clarify discrepancy in level of risk in protocol and ICF.
10.	JIP/IEC/SC/2013/5/439	<p>Investigator: Dr.Nisreen AR, Junior Resident, Dept. of Forensic Medicine,</p> <p>Guide:</p> <ol style="list-style-type: none"> 1. Dr.Sanjay Sukumar, Assistant Professor, Dept. of Forensic Medicine 2. Dr.Kusakumar Shaha, Associate Professor, Dept. of Forensic Medicine 	“ Socio-etiological aspects in dowry death cases – a medico-legal analysis ”	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Mention in the objectives that awareness will be generated regarding dowry deaths in Puducherry in the public domain, by publishing this study and its findings. • Confidentiality of participation will be maintained after anonymizing the data. • Granted waiver for taking informed consent.
11.	JIP/IEC/SC/2013/5/440	<p>Investigator: Dr.Rupesh Kumar Naik.B Junior Resident, Dept. Of Forensic Medicine,</p> <p>Guide:</p> <ol style="list-style-type: none"> 1. Dr.Siddhartha Das, Assistant Professor, Dept. of Forensic Medicine, 2. Dr.Kusa Kumar Shaha, Associate Professor, Dept. of Forensic Medicine 	Pattern of thoraco-abdominal injuries sustained in road traffic accidents: an autopsy based observational study.	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Ensure that identity of the subjects will not be disclosed - under ethical issues • Granted waiver for taking informed consent.
12.	JIP/IEC/2013/4/194	<p>Investigator: Dr. T.S. Ravikumar, Director, JIPMER, Dr. Gautam Roy, Prof and Head PSM Dr. Jerrold Ellner, USA Dr. Padmini S, USA</p> <p>Co-Investigators</p> <ol style="list-style-type: none"> 1. Dr. Sonali Sarkar, AP, PSM 2. Dr. Jharna M, AP, Microbiology 	Biomarkers for Risk of TB and for TB Treatment Failure and Relapse	<p>Approved with following corrections:</p> <ul style="list-style-type: none"> • Mention compensation will be provided for loss of wages, research related injury and risks as per JIPMER guidelines. • Mention that biological samples will be stored only for testing of TB biomarkers in future and not for any other purposes. • Change approval will be obtained from

		3. Dr. Vinod Kumar, Prof, Dept of TB and chest, 4. Dr Rakhi B, AP, Microbiology 5. Dr. Swaroop S, AP, PSM 6. Dr. Raman, Director, DOH&FW Services, 7. Mr. Muthuraj, Bacteriologist, Govt hospital for chest diseases 8. Dr. Subitha L, SR, PSM		“Institutional Review Board” to “Institute Ethics Committee”.
13.	JIP/IEC/SC/2/2012/31	Investigator Dr. Steven Aibor Dkhar, Professor, Dept. of Pharmacology Co-investigators 1. Dr. C. Adithan, Senior Professor & Head, Dept. of Clinical Pharmacology 2. Dr. Santhosh Sathesh, Additional Prof & Head, Dept. of Cardiology 3. Dr. K.V.Vinod, Associate Prof, Dept. of Medicine 4. Dr. Bobby Zachariah, Prof, Dept. of Biochemistry 5. Ms. C. Indumathi, Ph.D. Scholar, Dept. of Pharmacology	Pharmacogenetics of lipid lowering response of atorvastatin among dyslipidemic Tamilian population	Approved
14.	JIP/IEC/2014/1/206	Investigator: Dr. Prabhat, M.D Student, Dept.Of Biochemistry Guide: Dr.R. Soundravally, Associate Professor, Dept. Of Biochemistry Co-Guide: Dr. T. Kadhavan, Associate Professor, Dept. Of Medicine, Jipmer Dr.Rahul Dhodapkar, Asst. Prof., Dept. of Microbiology	Effect of <i>carica papaya</i> leaf extract on platelet aggregation, membrane fluidity and p-selectin expression in dengue infection: a randomised controlled trial	Approved

***: 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.

Shri. 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)

1. Justice S. Nadamuni Retired District Judge of Pondicherry, No.60, IV Cross, Venkata Nagar, Puducherry. (Chairman)
2. Dr. C. Adithan, Professor & Head, Department of Clinical Pharmacology, JIPMER (Member Secretary)
3. Dr. A.K. Das, H.O.D, Department of Endocrinology, JIPMER (Member)
4. Dr. K.S. Reddy, Director, Regional Cancer Centre, JIPMER (Member)
5. Dr. Santosh Kumar,– Senior Professor, Dept. of Urology , JIPMER (Member)
6. Dr. Vasantha Muthuswamy, Sr. Deputy Director General, ICMR (Retd) (Member)
7. Dr. Nandini K. Kumar, Former Deputy Director General Sr. Grade, National Institute of Epidemiology, Chennai. (Member)
8. Dr. M.G. Sridhar, Professor of Biochemistry, JIPMER (Member)
9. Dr. Zile Singh, Professor & Head, Department of P&SM, Pondicherry institute of Medical Sciences, Kalapet, Puducherry (Member)
10. Dr. K. Chandrasekaran, ML, Ph.D., Associate Professor, Dr. Ambedkar Govt. Law College, Kalapet, Puducherry (Member)
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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1. PS to Director / Medical Superintendent / Dean / Professor-in charge – Research for information