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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-2/2014

Date: 28.02.2014

Minutes of second meeting of the Institute Ethics Committee (Human Studies) for the year 2014 held on 28.02.2014

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The Second 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 28.02.2014 (Friday) at 9.30 AM under the Chairmanship of Shri.S.Nadamuni, District Judge (Retd). On 28.02.2014, the meeting was attended by Dr. Zile Singh (Member), Dr.Santosh Kumar (Member), Dr. K. Chandrasekaran (Member), Dr. N. Sakthivel (member), Dr. M.G. Sridhar (Member), Mrs. M. Vasuki (Member), Dr. Nandini Kumar (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.

The committee approved the following:

1. Minutes of previous Institute Ethics Committee Meeting held on 29.01.2014 & 30.01.2014
2. Minutes of Sub Committee Meeting held on 12.02.2014

In the meeting a total of 11 proposals were discussed. After deliberations the following decisions were arrived at

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

Towards the end of the meeting, the member secretary asked suggestions of the committee members regarding revision of IEC certificate format, informed consent forms and assent forms in accordance with ICMR as well as Schedule Y guidelines. In response, the members gave suggestions regarding alterations required under compensation, storage of biological samples and maintenance of confidentiality in the ICF. Following discussion, it was decided that modified versions of the ICF as well as assent form will be circulated to the members and a decision regarding the implementation of the suggested changes will be taken in the next main committee meeting. With this the member secretary thanked all the members and concluded the session stating that the date of next IEC meeting will be announced after discussion with the chairman.

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 15-03-14. 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.

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.**

Sl.No	Ethics Committee No	Names of Investigators and Co-investigators / Guides / Co-guides	Titles of the Research Projects	Comments
1.	JIP/IEC/SC/2013/5/465	<p>Investigator: Karthik.P, SR, Dept. of CTVS</p> <p>Guide: Dr. Ram Sankar, Assistant Professor, Dept. of CTVS</p> <p>Co-Guide: 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	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Discrepancies between protocol submitted and projected power point presentation need to be corrected. • Justification for third objective- lung biopsy in patient group needs to be given as it is not repeated at follow-up. • Pathological grading of pulmonary arterial hypertension needs to be included in the protocol. • Clarify level of risk in protocol & ICF. • Mention duration of study. • Mention sample size with justification. • Clarify regarding benefits and compensation for participation in the study. • Tamil and English consent form should be in concordance. • Mention confidentiality will be maintained during participation, storage of records and publication. • Mention participant is free to withdraw from the study, without assigning any reasons. • Mention that free treatment will be given to the patient, as per JIPMER guidelines. • Delete the clause on storage of biological samples in ICF – 2. • Include assent form if children more than 7 yrs and less than 18 yrs in addition to consent form from parent/LAR.
2.	JIP/IEC/SC/2013/5/419	<p>Investigator: Dr. K.Sreenivasa Reddy, M.D. Junior Resident, Dept. of Nuclear Medicine</p> <p>Guide: Dr. Dhanapathi.H, Associate Professor, Dept. of Nuclear Medicine,</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Gunaseelan K, Associative Professor, Dept. of Radiotherapy, Regional Cancer Centre, 2. Dr. Biswajit D., Dept. of Medical Oncology, Regional Cancer Centre, 3. Madhusudhanan Ponnusamy, Assistant Professor, Dept. of Nuclear Medicine 	Effect of Samarium-153-Ethylene Diamine Tetra Methylene Phosphonate on Pain and Analgesic Requirement in Patients with Multiple Skeletal Metastases	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention designation of the investigator. • Mention that procedure will be done free of cost to the participants of the study. • Mention that free treatment will be given to the patient, as per JIPMER guidelines. • Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. • Avoid use of medical jargon and abbreviations without expansion in the protocol. • Revise the consent forms completely and explain to the patient in simple terms so that he can understand the procedures involved. • Tamil and English consent form should be in concordance. • Signature, name and address of witness need to be added

				in ICF-2.
3.	JIP/IEC/2014/2/270	<p>Investigator: Dr.Unni.S.Pillai, Senior Resident, Department of Medical Oncology, RCC</p> <p>Guide: Dr.Biswajit Dubashi, Associate professor, Department of Medical Oncology, RCC</p> <p>Co-Guide: 1. Dr.Kadambari.D, Professor of Surgery 2. Dr.Smita Kayal, Assistant Professor, Department of Medical Oncology, RCC 3. Dr.Dhanapathi Halanaik, Associate Professor, Department of Nuclear Medicine 4. Dr.Sadish Kumar @ Kamalanathan, Associate Professor, Department of Endocrinology 5. Dr.Naveen, Assistant Professor, Department of Physical Medicine and Rehabilitation</p>	Late effects of breast cancer treatment and outcome after corrective interventions	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention JSAC approval date. • Include co-investigator's signature. • Fill check list and include investigator's signature. • Protocol to be resubmitted as per IEC format. • Justify sample size calculation and methods used. • Mention that this is a pilot study and the study will be continued in the department. • Clarify level of risk in protocol and ICF. • Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. • Mention participant is free to withdraw from the study, without assigning any reasons. • Mention that free treatment will be given to the patient, as per JIPMER guidelines. • Delete the clause on storage of biological samples in ICF – 2. • Tamil and English consent form should be in concordance. • Avoid use of medical jargon and abbreviations without expansion in the protocol. • Revise the consent forms completely and explain to the patient in simple terms so that he can understand the procedures involved. • Clarify regarding benefits for participation in the study.
4.	JIP/IEC/2014/2/271	<p>Investigator: Dr.Pooja Sethi, Fellow, Dept. of Medical Oncology</p> <p>Guide: Dr. Smita Kayal, Assistant Professor, Dept. of Medical Oncology</p> <p>Co-Guide: 1. Dr. K. S. Reddy, Professor & Head, Dept. of Medical Oncology, Director, RCC 2. Dr. D. Biswajit, Assistant Professor, Dept. of Medical Oncology 3. Dr. D. G. Shewade, Professor, Dept. of Pharmacology</p>	Comparison of the efficacy of olanzapine, metoclopramide and domperidone for chemotherapy induced breakthrough nausea and vomiting	Investigator was absent.
5.	JIP/IEC/2014/2/272	<p>Investigator: Priyamvada P S,Assistant</p>	Body composition analysis in predialysis Chronic Kidney Disease	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Include declaration in the protocol.

		<p>Professor, Department of Nephrology</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr G K Pal, Professor, Department of Physiology 2. Dr Sadish Kumar, Associate Professor, Department of Endocrinology 3. Dr Sreejith Parameswaran, Associate Professor, Department of Nephrology 4. Dr R Jayasurya, Senior resident, Department of Nephrology 	<p>patients and its association with conventional markers of malnutrition in south Indian patients - A pilot study</p>	<ul style="list-style-type: none"> • Mention confidentiality will be maintained during participation, storage of records and publication. • Mention participant is free to withdraw from the study, without assigning any reasons. • Tamil and English consent form should be in concordance. • Signature, name and address of witness need to be added in ICF-2. • Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. • Mention that DEXA scan will be done free of cost to the participant of the study. • Avoid use of medical jargon and abbreviations without expansion in the protocol. • Revise the consent forms completely and explain to the patient in simple terms so that he can understand the procedures involved.
6.	JIP/IEC/2014/2/273	<p>Investigator: Priyamvada P S, Assistant Professor, Department of Nephrology</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> 1. Dr Mukta Wyawahare, Associate Professor, Department of Medicine 2. Dr Vijayshankar, Senior resident, Department of Nephrology 3. Dr BH Srinivas, Assistant Professor, Department of Pathology 4. Dr Biju Pottakkat, Assistant Professor, Department of Surgical Gastroenterology 	<p>Renal-histopathological profile in patients succumbing with jaundice and acute renal failure – A Postmortem study</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Consent to be taken from LAR. • Make relevant changes in the information to the participants of the study in the consent form as it is a postmortem study. • Remove the clause on unconditional withdrawal from the study. • Written permission from the concerned departmental Heads need to be taken before commencement of the study and subsequently for each case which needs to be documented. • Benefits from the study to society need to be delineated in ICF. • Mention confidentiality will be maintained during participation, storage of records and publication. • Signature, name and address of witness need to be added in ICF-2.
7.	JIP/IEC/2014/2/274	<p>Investigator: Dr. Shivanand Kattimani, Assistant Professor, Department of Psychiatry</p> <p>Co-Investigator: Mr. Arivazhagan K, Clinical psychologist cum tutor, Department of Psychiatry</p>	<p>Stigma and its correlates in schizophrenia and related psychotic disorders: a multi centric cross-sectional study</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Revise ICF as per JIPMER IEC format. • Include consent from LAR (surrogate consent) in addition to consent taken from the patient. • Include signature of the investigators on the declaration page. • Mention confidentiality will be maintained during participation, storage of records and publication. • Investigator's signature, signature, name and address of

				witness need to be added in ICF-2. <ul style="list-style-type: none"> Clarify regarding level of risk.
8.	JIP/IEC/2014/2/275	<p>Investigator: Dr.Shivanand Kattimani, Assistant Professor, Department of Psychiatry</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> Dr.Ravi Philip Rajkumar, Assistant Professor, Department of Psychiatry Mr.Arivazhagan K, Clinical psychologist cum tutor, Department of Psychiatry 	Adapting ACE-III, a dementia screening questionnaire for Tamil speaking population.	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Revise ICF as per JIPMER IEC format. Clarify regarding level of risk. Mention exemption from getting consent is not asked for in protocol. Signature, name and address of witness need to be added in ICF-2. Include consent from LAR (surrogate consent) in addition to consent taken from the participant.
9.	JIP/IEC/SC/2014/1/544	<p>Investigator: Dr.Thiraviyam .E, Dept. of Radiotherapy</p> <p>Guide: Dr. Ashutosh Mukherji, Associate Professor, Department Of Radiotherapy</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> Dr.S.Vivekanandam, Professor and Head, Dept. of Radiotherapy Dr. Sunil Kumar Saxena, Professor And Head, Dept. Of Otorhinolaryngology Mr. N. Vijayprabhu, Lecturer In Radiology (Medical Physics), Department Of Radiotherapy 	Effect on quality of life and cochlear function sparing with use of volumetric modulated arc therapy and simultaneous integrated boost in cancers of head and neck	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Avoid use of medical jargon and abbreviations without expansion in the protocol. Revise the consent forms completely and explain to the patient in simple terms so that he can understand the procedures involved. Include signature of the investigators on the declaration page with title of the project. Mention that free treatment will be given to the patient, as per JIPMER guidelines. Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. The starting date of the study should be after IEC approval. Clarify level of risk in protocol & ICF. Mention alternate treatments available for the patient in the protocol. Tamil and English consent form should be in concordance. Mention participant is free to withdraw from the study, without assigning any reasons. Contact person whose details are given in the ICF should be the consultant involved as guide in this study.
10.	JIP/IEC/2014/2/276	<p>Investigator: Dr. Vikram Kate, Professor, Department of Surgery</p> <p>Co-Investigator:</p> <ol style="list-style-type: none"> Dr. Pankaj Kundra, Professor and Head, Department of Anaesthesiology Dr. S. Suresh Kumar, Assistant Professor, Department of Surgery Dr. Mahalakshmy T, Assistant 	Assessing risk factors for the development of Venous Thromboembolism (VTE) in surgical patients using Adapted Caprini Scoring System	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> Mention JSAC approval date. Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. Mention participant is free to withdraw from the study, without assigning any reasons. Mention that free treatment will be given to the patient, as per JIPMER guidelines. Mention possible interventions for prophylaxis.

		<p>Professor, Department of PSM</p> <p>4. Dr. Kanchan Bilgi, Junior Resident, Department of Anaesthesiology</p> <p>5. Dr. Arun Kumar, Junior Resident, Department of surgery</p>		<ul style="list-style-type: none"> • Include assent form if children more than 7 yrs and less than 18 yrs in addition to consent form from parent/LAR. • Mention confidentiality will be maintained during participation, storage of records and publication. • Signature, name and address of witness need to be added in ICF-2. • Tamil and English consent form should be in concordance. • Benefits from the study to society need to be delineated in ICF.
11.	JIP/IEC/SC/2014/1/545	<p>Investigator: Dr. Karimi Prashob Kumar, Senior Resident, Dept. of Surgical Oncology</p> <p>Guide: Dr.T.S.Ravikumar, Head of Dept., Dept. of Surgical Oncology</p> <p>Co-Guide:</p> <ol style="list-style-type: none"> 1. Dr. Aravind Ramkumar, Associate Professor, Dept. of Surgical Oncology 2. Dr.Kayal Smita, Assistant professor, Dept. of Medial Oncology 3. Dr.Ashutosh Mukarjhee, Assistant professor, Dept. of Radiation Oncology, 4. Dr.Shyama Prem S, Assistant Professor, Dept. of Radiation Oncology 	<p>Clinical outcomes and its determinants in patients undergoing D2 Gastrectomy followed by Chemoradiotherapy</p>	<p>Approved subject to following corrections:</p> <ul style="list-style-type: none"> • Mention JSAC approval date. • Exemption from taking ICF not granted. • Tamil ICF needs to be submitted. • Remove the clause regarding DCGI approval required in the protocol. • Include assent form if children more than 7 yrs and less than 18 yrs in addition to consent form from parent/LAR. • Avoid use of medical jargon and abbreviations without expansion in the protocol. • Clarify regarding compensation for participation in the study as well as foreseeable, unforeseeable risks, disability and death. • Include declaration in the protocol. • Mention sample size with justification. • Mention duration of study. • Modify statistical analysis as required..

☐: 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.

Chairman,
Institute Ethics Committee
(HUMAN STUDIES)

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