

NATIONAL ETHICS COMMITTEE
(ECR/534/Inst/OD/2014)

All India Institute of Medical Sciences Bhubaneswar,
Village Sijua, Patrapada, PO Dumduma, Bhubaneswar
751019, Odisha
Email: iec.aiimsbbsr@gmail.com
Phone:

To: Dr. Sujit Tripathy (Principal Investigator)

Date: 06.05.16

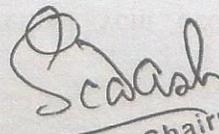
Re: IEC Proposal: T/IM-F/Ortho/15/16

Title: Association of vitamin D deficiency and knee osteoarthritis in non-obese and non-diabetic patients.

I am pleased to inform you that at the convened meeting of 23.04.2016, the IEC voted to approve an amendment and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
 2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
 3. Adverse events should be reported to the IRB. New Information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
 4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC may conduct audits of all study records, and consent documentation may be part of such audits.
 5. IEC-AIIMS needs review of an approved study not less than once per 12-month period. Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
 6. Principal investigator should initiate the project only after obtaining administrative permission from Director/Dean, AIIMS, Bhubaneswar.
- Sincerely,

Chairman, IEC



Chairman
National Ethics Committee
AIIMS Bhubaneswar-751019

Members of the IEC who voted in Favour of the Proposal

Dr. Debasish Hota, Dr Manaswini Mangaraj, Ms. Pranita Acharya, Dr. Swagata Tripathy, Ms. Swarna Misra, Dr. Somnath Mukherjee, Dr SC Dash. Dr Amit Ghosh

Chairperson of IEC-AIIMS BBSR

Dr. Suresh Chandra Dash
(Clinician)

Members of IEC AIIMS BBSR

Prof Debasis Hota
(Pharmacologist)

Dr K C Misra
(Scholar & Academician)

Dr Manaswini Mangaraj
(Basic Scientist)

Mr. Surendra Kumar Patri
(Lawyer)

Dr Amit Ghosh
(Basic Scientist)

Dr Ashish Patnaik
(Clinician)

Dr Swagata Tripathy (Clinician)

Ms. Swarna Misra
(Social Scientist)

Ms Pranita Acharya
(General community
representative)

Member- Secretary

Dr Somnath Mukherjee

Received
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