



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

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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 Swagatha Tripathy
(Clinician)

Ms. Swarna Misra
(Social Scientist)

Ms Pranita Acharya
(General community
representative)

Member- Secretary

Dr Somnath Mukherjee

To: Dr. Vikas Bhatia (Principal Investigator)

Date: 10.05.16

Re: IEC Proposal: T/EM -F/CMFM/16/02

Title: **Swabhiman- a nutritional intervention program in Odisha.**
Pre-implementation status assessment.

I am pleased to inform you that at the convened meeting of 07.05.2016, 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

Members of the IEC who voted in Favour of the Proposal

Dr. Debasish Hota, Dr. Manaswini Mangaraj, Dr Amit Ghosh, Dr. Swagata Tripathy, Dr. K C Mishra, Dr. Somnath Mukherjee.

अखिल भारतीय आयुर्विज्ञान संस्थान, भुवनेश्वर - ७५१ ०१९
RESEARCH CELL
All India Institute of Medical Sciences, Bhubaneswar-751 019



AIIMS-BBSR/RC/EM-F/02/2016/05

Dt: 13/05/2016

Dr. Vikas Bhatia
Professor & Head
Department of Community Medicine & Family Medicine

Subject: Regarding initiation of extramural research project.

Dear Prof. Bhatia,

The research cell is pleased to inform you that your extramural funded project entitled “**Swabhimana nutritional intervention program in Odisha, Pre-implementation status assessment**” (bearing provisional project code T/EM-F/CMFM/16/02 and IEC approval letter No T/EM-F/CMFM/16/02 dated 10.05.2016) has been examined and approved by the competent authority.

Kindly note that following the approval, you have been assigned permanent project code: P/EM-F/CMFM/16/02 and the study may be initiated in the institute.

You are requested to provide 6 monthly progress reports (in case study duration is longer than 6 months) and a consolidated summary report within 1 month of end of study to the research cell.

Thanking You

Yours sincerely

Dr. Dilip Kumar Parida,
Faculty-in-Charge, Research Cell

Dept. of CM & FM
AIIMS, BBSR
Date of Receipt.....14/05/16
Date of Despatched.....

[Handwritten signature of Dr. Dilip Kumar Parida]
13/5/16

[Handwritten note: Project file]
13/05/16

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