



## INSTITUTIONAL ETHICS COMMITTEE

Registration No: ECR/534/Inst/OD/2014/RR-17)

All India Institute of Medical Sciences  
Bhubaneswar

Level 3 Academic Block, AIIMS Bhubaneswar (At Sijua)  
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Date: September 16, 2019

### Chairperson

Dr Suresh Chandra Dash

### Members

Dr Manaswini Mangaraj  
(Basic Scientist)

Ms Navaneeta Rath  
(Social Scientist)

Ms Swarna Misra  
(General community  
representative)

Mr. Santanu Sarangi  
(Legal Person)

Dr Sandip Mishra  
(Basic Scientist)

Dr S. Manwar Ali  
(Clinician)

Dr Bikram Kishore Behera  
(Clinician)

Dr Rituparna Maiti  
(Pharmacologist)

Dr Somnath Mukherjee  
(Clinician)

Dr Amit Ghosh  
(Basic Scientist)

### Member- Secretary

Dr Arvind Kumar Singh

### Dr Balamurugan Ramadass

Assistant Professor,  
Department of Biochemistry,  
AIIMS, Bhubaneswar

Ref Number: T/EMF/Biochem/19/04

**Subject: What is the effect of a dietary resistant starch intervention on the colonic luminal environment and HIV-related immunity and is a feeding trial feasible in HIV-positive adults in India?**

Dear Dr Balamurugan Ramadass,

This is regarding your above-mentioned project proposal which was discussed in the Institutional Ethics Committee, AIIMS Bhubaneswar meeting held on July 13, 2019 (Saturday) and your subsequent letter dated September 14, 2019 responding to queries raised during IEC meeting.

The study is approved from ethical angle prospectively with effect from **September 16, 2019** till the entire period of the conduct of study according to the study duration mentioned in the protocol under direct responsibility of Dr Balamurugan Ramadass, Principal Investigator.

*As a Principal Investigator, you are responsible for following requirements as applicable for the present protocol.*

1. All co-investigators must be kept informed of the status of the project.
2. Obtain HMSC approval before initiation of the study and inform IEC after the approval.
3. No significant change to the protocol should be made and implemented without prior intimation and approval of the IEC
4. IEC should be reported about all Serious Adverse Events (SAEs) occurring during the study.
5. Only approved informed consent form and participant information sheet to be used for enrolment of the participants. All consent forms and other documents must be archived safely with PI for IEC audit
6. A six-monthly study progress report of the project must be submitted to IEC
7. It is hereby confirmed that neither you nor any of the study team members have participated in the voting/ decision making process of Institute Ethics Committee of AIIMS Bhubaneswar related to this study.

### Member who attended the meeting and voted in favour:

1. Dr Suresh Chandra Dash (Chairperson)
2. Dr Manaswini Mangaraj
3. Mr. Santanu Sarangi
4. Dr Sandip Mishra
5. Dr Rituparna Maiti
6. Dr S. Manwar Ali
7. Dr Bikram Kishore Behera
8. Dr Amit Ghosh.

Chairperson  
(IEC AIIMS Bhubaneswar)