



आरोग्यम् सुखं सम्पदा

Institute Ethics Committee

अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)

All India Institute of Medical Sciences, Raipur(Chhattisgarh)

Department of Pharmacology

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Raipur-492 099 (CG)

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Ethics Committee Registration No.: ECR/714/Inst/CT/2015

Letter No.: 114/IEC-AIIMSRPR/2016

Date: 02.09.2016

CERTIFICATE OF APPROVAL

To : Dr. Manisha Ruikar (Principal Investigator)
Professor & Head, Department of Community & Family Medicine,
AIIMS Raipur (CG)

Review Date : 06.08.2016

Reference : IEC Proposal No: **AIIMSRPR/IEC/2016/042**

Title : Baseline Survey for Swabhimaan Project, Bastar Block and Bakavand
Block, Bastar District (Developed in consultation with UNICEF)

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 06.08.2016.

The following documents were reviewed.

1. Covering Letter
2. Research Project Proposal (Version 2.0)
3. Case Record Form (Version 1.0)
4. Participant information sheet for participants more than 18 years of age (English & Hindi) (Version 1.0)
5. Participant information sheet for participants less than 18 years of age - English & Hindi (Version 1.0)
6. Consent Form for participant more than 18 year of age (English & Hindi) (Version 1.0)
7. Assent Form - English & Hindi (Version 1.0)
8. Undertaking regarding GCP guidelines and reporting of SAE
9. Other documents

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- a. Duly signed compliance sheet submitted to IEC by PI alongwith following documents :
- i. E-communication by Dr Abner Daniel, Nutrition Specialist, Child Development and Nutrition, UNICEF to the Principal Investigator
 - ii. Letter by Director, National Rural Livelihood Promotion Society to Mision Director, Chhattisgarh Gramin Ajjevika Samvardaan Samiti
 - iii. Letter by Mission Director, SRLM, Chhattisgarh to the Chief, Field Office , UNICEF

The following members of Institute Ethics Committee were present at the meeting held on 06.08.2016 at 11:00 AM at Department of Pharmacology, AIIMS Raipur.

Sr. No.	Name of IEC Member	Designation
1	Dr. Arun T. Dabke Ex. Vice-chancellor Ayush and Health Science University Raipur (CG)	Chairman
2	Dr. S. R. Gupta M.D. (Med.), M.D. Pharmacology Retired Professor & Head Department of Medicine Pt. J. N. M. Medical College, Raipur	Basic Medical Scientist
3	Dr. P. K. Neema Professor and Head Department of Anaesthesiology AIIMS Raipur	Clinician
4	Dr. Sarita Agrawal Professor and Head Department of Obstetrics and Gynaecology AIIMS Raipur	Clinician
5	Mrs. Kamla Janswami Ex-president Lion's Club, Raipur	Lay Person from Community
6	Ms. Pushpy Michael Principal Bharatmata Higher Secondary School GE Road, Tatibandh, Raipur Chhattisgarh	Social Scientist
7	Dr. Nitin Gaikwad Associate Professor Department of Pharmacology AIIMS Raipur	Member Secretary
Outside Legal Expert		
8	Advocate Shekhar Amin	Legal Expert

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Clear statement of decision reached:

At Institute Ethics Committee meeting held on 06.08.2016, the committee reviewed the research project and study related documents and discussed the ethical issues involved.

A letter to this effect was sent to you seeking certain clarifications / modifications vide letter no. 104/IEC-AIIMSRPR/2016, dated 19.08.2016. In response to this, you have submitted required clarifications / modifications vide letter no. CFM/MR/Project/348/2016 dated 24.08.2016 (IEC inward letter no. 2016/84 dated 25.08.2016). Therefore, the research project and study related documents are approved with respect to ethical issues.

Hence, at the convened meeting of IEC-AIIMS Raipur on 02.09.2016, IEC decided to **approve** the above referenced research project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. This approval is valid for entire duration of the study (i.e. Six months). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
2. All the co-investigators must be kept informed of the status of the project.
3. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
4. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
5. The IEC proposal number assigned to the project should be cited in any correspondence.
6. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
7. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
8. 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


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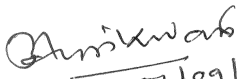
IEC may conduct audits of all study records, and consent documentation may be part of such audits.

9. The study progress report should be made available for the IEC review on every 6 month.
10. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

Sincerely,


Dr. Arun T. Dabke
Chairman
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)
2/9/16


Dr. Nitin Gaikwad
Member Secretary
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)
02/09/2016