

Impact Assessment Study of Rotavirus Vaccine

Memorandum of Understanding

between



Christian Medical College (CMC), Vellore

&



KIIT School of Public Health, Bhubaneswar

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding (MOU) is made between:

The Principal, Christian Medical College (CMC), Vellore on one hand, on this day of January, 2016 and

The Director, KIIT School of Public Health, Bhubaneswar on the other hand

This project, the 'Impact Assessment Study of Rotavirus Vaccine' funded by the CDC Foundation, Atlanta with the Christian Medical College (CMC), Vellore as the primary grantee, with the Indian Council for Medical Research (ICMR) and the National Institute of Epidemiology (NIE) as partners, is approved by the Health Ministry Screening Committee and will generate data on effectiveness and impact of rotavirus vaccines through UIP in early introducing regions of India (Odisha, Andhra Pradesh, Haryana, and Himachal Pradesh) and will establish a sentinel site-based platform for assessment of safety of the vaccine with respect to intussusception. The effectiveness and impact evaluations will focus on the early adopter regions of ROTAVAC and will be built on the existing infrastructure of the National Rotavirus Surveillance Network (NRSN), a national network of sentinel hospital-based sites across India conducting AGE surveillance, with strengthening of sites included for impact assessment in early introducing states.

The Christian Medical College Vellore, in association with Indian Council of Medical Research (ICMR), New Delhi and National Institute of Epidemiology, is carrying out a Taskforce Project on 'Impact Assessment Study of Rotavirus Vaccine' funded by the Centers for Disease Control and Prevention Foundation, Atlanta. Christian Medical College, Vellore has been engaged by ICMR as the nodal agency/ coordinating center for the conduct of the project involving approximately thirteen partner institutions (peripheral centers) for each of which the Principal, Christian Medical College will enter into a separate MOU in phased manner.

ICMR set up the National Rotavirus Surveillance Network which is a National hospital based surveillance for rotavirus diarrhea in 2005, which has been functioning in different parts of the country since then, with one centre in your state. In view of the introduction of the rotavirus vaccine through the Universal Immunization Program (UIP), it is decided to expand this surveillance activity.

And, whereas **Christian Medical College (CMC), Vellore** is one of these aforementioned partner institutions identified as a **referral laboratory** and has been tasked, *inter alia*, with the following responsibilities in order to ensure smooth execution of the deliverables as follows:

- CMC Vellore will identify potential sentinel sites with ICMR, engage in discussions and develop sub-contracts for financial support.

- CMC will conduct training workshops for the sentinel sites, and coordinate monitoring and evaluation of the sentinel sites under the direction of ICMR.
- CMC will receive samples and Case Report Forms (CRFs) from the sites and do the data entry.
- CMC will test all samples and conduct ELISA for screening and PCR for genotyping as needed.
- CMC will coordinate with NIE and CDC, under the direction of ICMR for periodic summary reporting and data analysis.
- CMC and NIE will coordinate meetings for data analysis and sharing.

And whereas, the sentinel site i.e. **KIIT School of Public Health, Bhubaneswar**, will fulfill the following obligations under this MOU to enable the Principal, Christian Medical College (CMC) to carry out the responsibilities as detailed herein above:

- Each Sentinel Site/Hospital will enroll all admitted and eligible cases of AGE (estimated 500 cases per site per year) during the study.
- Each site will complete CRFs for each enrolled patient after informed consent and undertake sample collection by trained project personnel.
- A detailed immunization history will be obtained from the patient's relatives and a vaccination card copy will be obtained (Xerox Copy) by the study personnel.
- A diarrhea log book must be maintained as per the protocol. The stool sample must be stored at -20⁰C (Freezer of the refrigerator) until shipping.
- Each site will send samples monthly to CMC Vellore in Vaccine Carrier or Thermocol box with frozen gel packs along with completed original CRFs (a Xerox copy to be retained at the site) and copy of respective Forms 2 and 3 and Sample Shipment Form.

The collection of immunization information is critical for the success of the impact evaluation. Therefore, a key parameter of the evaluation of the sites' performance will be the ability to collect information and documentary evidence of a child's immunization history.

Force Majeure

No failure or delay or omission by all parties to fulfill any of its obligations under this MOU (other than the obligations mentioned herein with a view to coordinate the timely execution of the deliverables) shall give rise to any claim against such party or be declared to be breach of this MOU if any, to the extent such failure, delay or omissions arises from the unplanned event not within the reasonable control of such party.

The progress during the period of the survey will be reviewed periodically by CMC, ICMR and necessary mid-course corrections will be made to resolve the problems, if any, in any aspect pertaining to the study faced by NIE, partner institutions, or related agencies.

And, whereas in order to enable partner institutes to effectively discharge their respective responsibilities and obligations under this MOU, the Principal, Christian Medical College (CMC) and the Director, KIIT School of Public Health, Bhubaneswar, do hereby commit to put in place effective systems to deliver on the measurable outcomes set out in this MOU.

All data from the study will be published in peer-reviewed journals and included in reports to the government and the World Health Organization. No data will be published without inclusion of site investigators as co-authors on publications. Where appropriate, summary presentations of site data may be presented to national authorities, duly acknowledging sites. Investigators will retain a copy of all CRFs and can analyze their own data. If help with analysis is required, CMC will support any analysis requested by the site.

Appendix I contain the budget approved for the site for the period of six months.

The funds in Appendix I is for the period of six months. Site project extension is based on the performance appraisal of the Christian Medical College, Vellore at the end of six months.

The Principal Investigator for the KIMS, KIIT School of Public Health is Dr. Nirmal Mohakud, Assistant Professor, Department of Pediatrics, and Co-Investigator is Mr. Dipty Mohanty, Public Health Specialist, KIIT School of Public Health, Bhubaneswar.

The Principal, Christian Medical College (CMC), and The Director, KIIT School of Public Health, Bhubaneswar, having accepted the respective responsibilities and obligations described in this Memorandum and having agreed to the terms and conditions contained herein, do set their hands to this MOU on this theth day of January 2016.

The MOU shall remain in force for a period of 4 years from the date of its signature and seal, and may be terminated by either side by giving a six months notice to that effect in writing. However, notwithstanding the notice of the intent to terminate the memorandum, all rights, obligations and corresponding duties and subsisting therein shall be respected and mandated till the finalization of work and accomplishment thereof.

However, it is provided that the First Party shall have the right to drop any partner-institution which does not perform up to the mark of satisfaction after giving 60 days notice to that effect in writing.

The parties to this MOU undertake to treat as CONFIDENTIAL AND PRIVILEGED information of the other institution, which is so classified in advance. The terms of confidentiality and mode of disclosure shall be as per mutually acceptable terms.



Principal
Christian Medical College
Vellore

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Director
KIIT School of Public Health
Bhubaneswar
Director

KIIT School of Public Health (KSPH)
KIIT University, Bhubaneswar-751024

Budget Impact assessment Study of Rotavirus Vaccine Linked to the National Rotavirus Surveillance Network

(Budget for 6 months)

| Si. No | Particulars | No. | Monthly | For 6 Months |
|----------|---|-----|-------------------------------------|---------------|
| A | Man Power | | | |
| | Project Medical Officer (Partly) | 1 | 35000 | 210000 |
| | Lab Technician | 1 | 15000 | 90000 |
| | Field Worker | 2 | 15000 | 180000 |
| | Sub Total | | | 480000 |
| B | Procurement | | | |
| | Computer with Peripherals | | | 60000 |
| | Sample Collection Container | | | 10000 |
| | Deep freezer (-20 ⁰ C) | | | 30000 |
| | Other (office & Lab support) | | | 7500 |
| | Sub Total | | | 107500 |
| C | Travel | | | |
| | <u>Local@4000 for 6 Months</u> | | | 24000 |
| | Sub Total | | | 24000 |
| F | Shipment of Sample (2times/Month):6nos. (through cold chain) | 6 | 5000 per shipment Approximate | 30000 |
| D | Institutional Overhead (10%) | | | 64150 |
| E | Total | | | 705650 |

(Total Seven Lakhs Five Thousand Six Hundred Fifty Rupees only)