File No: BIO/CT/19/000036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06
(See rules 22, 25, 26, 29 and 30)
Permission to conduct clinical trial of new drug or investigational new drug

The Central Licensing Authority hereby permits Mr. Dinesh Kumar Sood of M/s Serum Institute Of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune (India) - 411028 Telephone No.: 020-26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail:SSJ@SERUMINSTITUTE.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: PCV-10-004 Version No. 1.0 Protocol Date 29-MAR-2019 in the below mentioned clinical trial sites.

CT No.: CT- 18/2019

Details of new drug or investigational new drug:	
Names of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent)
Therapeutic class:	Vaccine
Dosage form:	Vaccine (Liquid)
Composition:	Saccharide for each serotypes 1,5, 6A, 7F, 9V, 14, 19A, 19F and 23F conjugated with CRM197 =2.0000 micrograms (µg), Active Saccharide for serotype 6B conjugated with CRM197 =4.0000 micrograms (µg), Active Aluminium (as Aluminium phosphate) =0.1250 milligram (mg), Inactive Thiomersal (only for multidose) =0.0050 %
Indication:	Active immunization for the prevention of disease caused by *Streptococcus Pneumoniae*, including sepsis, meningitis, bacteraemia, pneumonia and acute otitis media.

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Pediatric Research Cell, Department of Pediatrics, Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Dhankawadi, Katraj, Pune-411043, Maharashtra.	Institutional Ethics Committee Bharati Vidyapeeth Deemed University 4th Floor, Bharati Hospital & Research CentrePune-Satara Road, Katraj – Dhankawadi Pune -411043, Maharashtra. Ethics Committee Registration no: ECR/313/Inst/MH/2013/RR-16	Dr. Sanjay Kewalchand Lalwani
2	KEM Hospital Research Centre,Vadu Rural Health Program, A/P-Vadu Budruk, Taluka- Shirur, District Pune -	KEM Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth Pune 411011, Maharashtra, India Ethics Committee Registration no:	Dr. Ashish Ramesh Bavdekar

	412216, Maharashtra	ECR/272/Inst/MH/2013/RR-16	
3	Well Baby Immunization Clinic, Department of Pediatrics -1, Christian Medical College, Vellore-632004, Tamil Nadu	Institutional Review Board (IRB), Christian Medical College, Vellore-632002 Tamil Nadu. Ethics Committee Registration no: ECR/326/Inst/TN/2013/RR-16	Dr. Rajeev Zachariah Kompithra
4	Department of Pediatrics, KLES Dr Prabhakar Kore Hospital and MRC, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi - 590010, Karnataka	Institutional Ethics Committee, JNMC,Campus, Nehru Nagar, Belagavi-590010, Karanataka Ethics Committee Registration no: ECR/211/Inst/KA/2013/RR- 2016	Dr. Niranjana Mahantshetti
5	Sri Ramachandra Institute of Higher Education and Research (DU) Clinical Research Division, Dental College Basement, No.1 Ramachandra Nagar, Porur, Chennai - 600 116, Tamil Nadu	Institutional Ethics Committee,Sri Ramachandra Institute of Higher Education & Research (DU), No.1, Ramachandra Nagar, Porur, Chennai-600116, Tamil Nadu Ethics Committee Registration no:ECR/203/Inst/TN/2013/RR-16	Dr. Padmasani Venkat Ramanan
6	Department of Pediatrics, Institute of Child Health, 11, Dr. Biresh Guha Street; Kolkata, West Bengal-700017	Institutional Ethics Committee-Institute of Child Health11, Dr. Biresh Guha Street, KolKata- 700017, West Bengal Ethics Committee Registration no:ECR/359/Inst/WB/2013/RR-16	Dr. Apurba Ghosh
7	Hamdard Institute of Medical Sciences and Research (HIMSR), and Associated Hakeem Abdul Hameed Centenary Hospital (HAHCH) Jamia Hamdard, Hamdard Nagar,New Delhi – 110062	Jamia Hamdard Institutional Ethics Committee Basement, Nano Biotechnology Building,Jamia Hamdard, Hamdard Nagar,New Delhi – 110062 Ethics Committee Registration no: ECR/48/Inst/DL/2013/RR-16	Dr. Chandra Mohan Kumar
8	Department of Paediatrics, Shri Maharaja Gulab Singh (SMGS) Hospital, Government Medical College, Jammu – 180001	Institutional Ethics Committee, Government Medical College, Bakshi Nagar, Jammu, Jammu & Kashmir 180001 Ethics Committee Registration no: ECR/454/Inst/JK/2013/RR-16	Dr. Dinesh Kumar

Conditions of permission for conduct of clinical trial-

The permission granted by the Central Licencing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:-

(I) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;

(II) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site;

or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(III) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(IV) The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

(V) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

(VI) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(VII) Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(VIII) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

(IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

(X) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

(XI) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

(XII) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

(XIII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

(XIV) Where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

(XV) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(XVI) The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

(XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XVIII) The enrolment for this clinical trial (2+1) shall be initiated after the completion of final dosing of the last subject in phase III (3+0) clinical trial.

(XIX) To submit Ethics Committee approvals of all the participating sites for clinical trial protocol before initiation of the clinical trial.

(XX) Only CDL, Kasauli certified batches shall be used in the clinical trial.

Yours faithfully,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION ., 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59a6f4c3a02cb467e76d5edcdb3a731ee144, ou=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.08.13 17:02:36 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 13-AUG-2019