



Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 6
NOTICE OF APPROVAL

Date: 13 September 2021

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation in accordance with the International Conference on the Harmonization of Good Clinical Practice and the National Ethical Guidelines on Health and Health-related Research

SJREB Protocol No.:	SJREB-2021-76	Sponsor Protocol No.:	COVID-19-PRO-003
---------------------	---------------	-----------------------	------------------

Coordinating Investigator:	Dr. Joel Santiaguél	Sponsor:	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
----------------------------	---------------------	----------	---

Title:	A Multi-center, Randomized, Double-Blinded, Placebo-Controlled Phase 3 Clinical Trial of Influenza Virus Vector COVID-19 Vaccine for Intranasal Spray (DelNS1-2019-nCoV-RBD-OPT1) in Healthy Participants of 18 Years and Older		
--------	--	--	--

Protocol Version No.:	1. Protocol version 2.0 2. COVID-19-PRO-003 Philippines Addendum V1.0	Version Date:	1. 10 August 2021 2. 20 August 2021
-----------------------	--	---------------	--

ICF Version No.:	1. COVID-19-PRO-003 Master Version 2.0 – 12 Aug 2021_Philippines (English) v2.0 2. COVID-19-PRO-003 Master Version 2.0 – 12 Aug 2021_Philippines (Tagalog) v2.0	Version Date:	1. 20 August 2021 2. 20 August 2021
------------------	--	---------------	--

Other Documents:	
------------------	--

Members of research team:	<ol style="list-style-type: none"> 1. Dr. Joel Santiaguél 2. Dr. Anjuli Jaen 3. Dr. Loreta Zoleta 4. Dr. Louie Tirador 5. Dr. Ronald Payumo 6. Dr. Abundio Balgos 7. Dr. Evan Vista 8. Dr. Allen Zagala 9. Dr. Andrei Rodriguez 10. Dr. Gelza Mae Zabat 11. Dr. Ralph Villalobos 12. Dr. Ma. Philina-Villamor 13. Dr. Gemalyn Gueco 14. Dr. Grace Aquitania
---------------------------	---

Study sites:	<ol style="list-style-type: none"> 1. Quirino Memorial Medical Center 2. The Medical City Iloilo 3. Silang Specialist Medical Center 4. St. Paul's Hospital Iloilo 5. Mary Johnston Hospital 6. The Health Centrum Hospital 7. St. Luke's Medical Center, Global City 8. Premier Medical Center 9. Makati Medical Center 10. Tropical Disease Foundation 11. Philippine General Hospital 12. Cebu Institute of Medicine 13. Angeles University Foundation and Medical Center 14. Davao Medical Schools Foundation
--------------	---

Type of Review:	<input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Full Board Meeting date: August 11, 2021	Duration of Approval From – To (<i>date</i>) September 8, 2021 to September 8, 2022	Frequency of continuing review Annual
-----------------	--	--	--

SJREB Chair	Signature	Date
Dr. Jacinto Blas V. Mantaring III		September 14, 2021

Investigator Responsibilities after Approval:

- Submit country protocol amendments to the SJREB and site REC for approval before implementing them;

- Submit site-specific amendments to site REC for approval before implementing them;
- Submit annual report for renewal of approval to SJREB;
- Submit SAE and SUSAR reports to the site REC within 7 days;
- Submit progress report every 12 months;
- Submit final report after completion of protocol procedures at the study site;
- Report protocol deviation/violation to the REC study sites;
- Comply with all relevant international and national guidelines and regulations; and
- Abide by the principles of good clinical practice and ethical research

Received by:

Name: _____

Signature: _____

Date: _____