



# UNIVERSITY OF SANTO TOMAS HOSPITAL

## RESEARCH ETHICS COMMITTEE

6<sup>th</sup> Floor St. John Macias O.P. Building  
A.H. Lacson St., Sampaloc Manila 1015 Philippines  
Telephone: +63 2 8731-3001 local 2610  
Email: [usth\\_irb@yahoo.com.ph](mailto:usth_irb@yahoo.com.ph) Website: [usthrec.online](http://usthrec.online)



Date

### NAME

Designation

Department Affiliation

Institution

**Re:** Approval Letter to the Review of < New/Resubmitted > Protocol

**REC Protocol Reference No.:**

**Protocol No./Title:**

**Sponsor/CRO:**

Dear \_\_\_\_\_:

The **University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC)** acknowledges receipt of your < **Research Protocol Version No.** > and its related documents, submitted online on Date\_Month\_Year. These have been assessed through < **expedited/full** > review.

The REC is pleased to inform you that your < nature of study >, has been **APPROVED**.

**Validity of Ethics Approval: DATE\_MONTH\_YEAR to DATE\_MONTH\_YEAR**

Please be reminded that the study team must always adhere to the principles of *Good Clinical Practice (GCP)* and the *National Ethical Guidelines for Research Involving Human Participants (NEGRIHP) 2022*.

### The following responsibilities must be observed by the investigator after approval:

- Utilize USTH-REC stamped Informed Consent Forms (ICFs). Approved consent forms must include the USTH-REC stamp and the approval date in the document footer.
- Submit any amendments to the Protocol and/or Informed Consent Form (using **REC F14**) for approval prior to implementation.
- Apply for Continuing Review (using **REC F19**) for renewal of ethical clearance at least thirty (30) days before the expiration of the protocol approval; failure to do so will result in withdrawal of ethical clearance.
- Be advised that if a continuing review application is not submitted within one (1) year, the REC will implement standard procedures for non-compliance, which may lead to a recommendation for withdrawal of ethical clearance and subsequent inactivation and archiving of the study file.
- Submit Related Non-Events (RNE), Serious Adverse Events (SAE), and Suspected Unexpected Serious Adverse Reactions (SUSAR) reports (using **REC F15**) to the site REC within seven (7) days.



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- Report any Protocol Deviations or Violations (using **REC F16**) within seven (7) days upon detection.
- **Submit the Final Report** (using **REC F18**) **no later than eight (8) weeks after completing protocol procedures at the study site.**
- Submit an Early Termination Form (using **REC F17**) if the approved study is terminated prior to completion.
- Ensure compliance with all relevant international and national guidelines and regulations regarding the safety and protection of study participants.

The following items have been received, reviewed, and approved in connection with the study to be conducted by the investigator:

No.	Document Name	Version No.	Date
1	Research Protocol		
2	Informed Consent Forms		
3	CV & GCP Training Certificate of Investigators		
3.1			
3.2			

Furthermore, we would like to inform you that the **Research Ethics Committee** of the **University of Santo Tomas Hospital** is organized and operates according to the *International Council for Harmonisation – Good Clinical Practice (E6 R2)* guidelines, the *2022 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP)*, and all applicable laws and regulations.

For requests regarding REC forms or any inquiries, please contact us at **+63 2 8731-3001 local 2610** or visit the USTH REC website at **[usthrec.online](http://usthrec.online)**.

**For the USTH – Research Ethics Committee:**

**< SIGNATURE OVER PRINTED NAME >**  
REC Head



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### COMMITTEE COMPOSITION

Name of Institution: UNIVERSITY OF SANTO TOMAS HOSPITAL (USTH)				
Address of Institution: España Blvd., Manila, Philippines, 1015				
No.	Name of Member	REC Designation/ Department/Expertise	Affiliation w/ the institution	
			Yes	No
1		Head	<input type="checkbox"/>	<input type="checkbox"/>
2		Vice Head	<input type="checkbox"/>	<input type="checkbox"/>
3		Member Secretary	<input type="checkbox"/>	<input type="checkbox"/>
4		Regular Member	<input type="checkbox"/>	<input type="checkbox"/>
5		Regular Member	<input type="checkbox"/>	<input type="checkbox"/>
6		Regular Member	<input type="checkbox"/>	<input type="checkbox"/>
7		Regular Member	<input type="checkbox"/>	<input type="checkbox"/>
8		Regular Member	<input type="checkbox"/>	<input type="checkbox"/>
9		Regular Member Non-medical/Layperson	<input type="checkbox"/>	<input type="checkbox"/>

<b>Signed:</b>		
<b>USTH - REC Head</b>	<b>Printed Name &amp; Signature</b>	<b>Date of Approval</b>
	<b>REC Head</b>	Date_Month_Year