Date:

**NAME**

Designation

Department Affiliation

Institution

|  |  |  |  |
| --- | --- | --- | --- |
| **Re:** | Approval Letter to the Review of < Resubmitted Protocol > | | |
| **REC Protocol Reference No.:** | | | Click to enter text. |
| **Protocol No./**  **Title:** | | Click to enter text. | |
| **Sponsor/CRO:** | | Click to enter text. | |

**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 **< full/expedited review >.**

The REC has reviewed and approved your **< type of research >** study, which aims to **< indicate study objectives** >. This study will include **< indicate study population and study duration** >.

**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:**

* Use USTH-REC stamped ICFs. The REC-approved consent forms must be *“stamped”* and contain the approval date in the footer of the document
* 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.
* 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 | **Curriculum Vitae of Study Team** |  |  |
| 3.1 |  |  |  |
| 3.2 |  |  |  |
| 4 | **GCP Training Certificates of Study Team** |  |  |
| 4.1 |  |  |  |
| 4.2 |  |  |  |
| **5** | **Other Documents** |  |  |
| 5.1 |  |  |  |
|  |  |  |  |

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 Good Clinical Practice and 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.***

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

**< SIGNATURE OVER PRINTED NAME >**

REC Head

**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 |  |  |
| 2 |  | Vice Head |  |  |
| 3 |  | Member Secretary |  |  |
| 4 |  | Regular Member |  |  |
| 5 |  | Regular Member |  |  |
| 6 |  | Regular Member |  |  |
| 7 |  | Regular Member |  |  |
| 8 |  | Regular Member |  |  |
| 9 |  | Regular Member  Non-medical/Layperson |  |  |

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| --- | --- | --- |
| **Signed:** |  |  |
| **USTH - REC Head** | **Printed Name & Signature** | **Date of Approval** |
|  |  |  |

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| --- |
| ETHICS APPROVAL FORM 010225-MD-ST-IR-F12 rev6 |