|  |
| --- |
| **UNIVERSITY OF SANTO TOMAS HOSPITAL** RESEARCH ETHICS COMMITTEE 6th 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*  **UNIVERSITY OF SANTO TOMAS HOSPITAL** España Blvd., Manila logo copy |

Date:

**NAME**

Designation

Department Affiliation

Institution

|  |  |  |  |
| --- | --- | --- | --- |
| **Re:** | Action Letter to the Review of <New/Resubmitted Protocol/Amendment etc.> | | |
| **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 <**Revised/Amended Protocol Version No.>** submitted via online last **Date\_Month\_Year** which has been assessed through **expedited/full review**.

|  |  |
| --- | --- |
| **Items for Revision** | **Revision/information required** |
| 1. **In Protocol:** |  |
| 1. **Scientific Soundness:** |  |
| 1. **Technical Soundness:** |  |
| 1. **Ethical Soundness:** |  |
| 1. **In Informed Consent Forms:** |  |
| 1. **Others:** |  |

The <**MINOR/MAJOR MODIFICATIONS>** requested by the USTH-REC should be in accordance with the following:

1. Integrate into a revised research protocol &/or consent forms and related documents.
2. Submit revised protocols and consent forms in A4 size paper, Arial font size 12-point. Use double-spacing throughout, except partly in the title page.
3. Start a new page for every main document. Change the footer to indicate both the date (creation date) and version number). Modified part should be written in bold letters.
4. Use the ***USTH-REC Resubmission Form*** *(****F11*)** in submitting your revised research protocol and consent forms. Include a submission letter addressed to the REC Head.
5. Attach the REC issued letter of recommendations, comments & questions for reference of the reviewer.
6. Send the electronic copy to e-mail address: [***usth\_irb@yahoo.com.ph***](mailto:usth_irb@yahoo.com.ph)***.***
7. Submit one (1) set printed copy placed in ordinary folder at REC Office. Follow updated submission schedule effective **November 2021** as follows:

**Online submission:** *Every Wednesdays & Fridays not later than 12:00 midnight*

**Printed copy submission:** *Every Wednesdays & Fridays 9AM to 3PM*

**Submit your revised documents on or before:**  **Date\_Month Year**

If no resubmission is received within six (6) weeks after receiving this letter, the protocol will be considered **CANCELLED.**

Furthermore, please be reminded that ***all research protocols submitted to the USTH-REC for ethical review shall only be initiated once an approval is granted***.

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

(Signature)

(Name)

REC Head