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| Date**NAME** DesignationDepartment AffiliationInstitution

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| **Re:** | Action Letter to the Review of < New/Resubmitted/Amended **>** 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 via online portal on **<Date\_Month\_Year>**. These have been assessed through **<expedited/full> review.**Below are the specific scientific, technical, and ethical issues that require clarification or modification prior to further consideration and approval:1. **In Protocol:**
	1. **Scientific Soundness:**
	2. **Technical Soundness:**
	3. **Ethical Soundness:**
2. **In Informed Consent Forms:**
3. **Others:**

The **MINOR/ MAJOR MODIFICATIONS** requested by the USTH-REC must adhere to the following guidelines:1. Integrate the modifications into a revised research protocol, consent forms, and related documents, as applicable.
2. Submit revised protocols and consent forms on A4-sized paper, using Arial font at 12- point size. Please ensure double-spacing throughout, except for the title page.
3. Begin each main document on a new page. Update the footer to include both the creation date and version number. Any modified sections should be highlighted in bold.
4. Submit a properly accomplished, signed and dated REC Resubmission Form (F11) along with your revised research protocol and/or consent forms, as applicable.
5. Include a submission letter addressed to the Head of the REC.
6. Attach the REC-issued letter containing recommendations, comments, and questions for the reviewer's reference.
7. Submit an electronic copy of the revised documents via the USTH-REC website: **usthrec.online.**
8. Provide one printed copy, placed in an ordinary folder, to the REC Office.
9. Adhere to the updated submission schedule effective November 2021, as follows:
* Online submissions: Every Wednesday and Friday, no later than 12:00 midnight.
* Printed copy submissions: Every Wednesday and Friday, between 9:00 AM and 3:00 PM.

Please submit your revised documents not later than **<DATE\_MONTH\_YEAR>.**If no resubmission is received within four (4) weeks of this notification, the protocol will be considered **CANCELLED.****For the USTH – Research Ethics Committee:****< SIGNATURE OVER PRINTED NAME >**REC Head |