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| Date  **NAME**  Designation  Department Affiliation  Institution   |  |  |  |  | | --- | --- | --- | --- | | **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 |