**Final Report Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form is required upon completion of the study or closure of study site. If iREB is unavailable, obtain an electronic copy of this form and encode all information required in the space provided, and email this form at* [*upmreb@post.upm.edu.ph*](mailto:upmreb@post.upm.edu.ph)*. For protocols that have been issued a certificate of exemption, fill out only the applicable sections.*

|  |  |  |
| --- | --- | --- |
| **UPMREB CODE:** | | |
| **STUDY PROTOCOL TITLE:** | | |
| **PRINCIPAL INVESTIGATOR:** | | |
| **INITIAL APPROVAL DATE:** <dd/mm/yyyy> | | |
| **DATE OF EXEMPTION:** <dd/mm/yyyy> | | |
| **DATE OF LAST CONTINUING REVIEW APPROVAL:** <dd/mm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Version and date of latest approved protocol:** | | |
| **Version and date of latest approved ICF:** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE:** <Name and address> | | |
| **STUDY SITE ADDRESS:** | | |
| **SPONSOR:** | | |
| **SPONSOR CONTACT PERSON:** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **PHILIPPINE HEALTH RESEARCH REGISTRY (PHRR) ID** *(Registration in the PHRR is required for all researches)***:** | | |
| **REPORT SUBMISSION DATE:** (to be filled out by UPMREB) <dd/mm/yyyy> | | |
| 1. Period of data collection: <dd/mm/yyyy> to <dd/mm/yyyy> | | |
| 1. Study Arms: | | |
| 1. Number of study participants in the beginning of the study: | | |
| 1. Number of participants at the end of the study: | | |
| 1. Number of participants who received the test articles: | | |
| 1. Summary of amendments to the original protocol (including dates of approval): | | |
| 1. Summary of study non-compliance / protocol deviation reported: | | |
| 1. Summary of SAE reported: | | |
| 1. Summary of anticipated risks (other than SAEs) documented in the conduct of study: | | |
| 1. Summary of SUSAR reported: | | |
| 1. Summary of unanticipated risks (others than SUSAR) documented in the conduct of study: | | |
| 1. Summary of participants’ complaints or grievances documented regarding conduct of study: | | |
| 1. Summary of benefits documented: | | |
| 1. Summary of indemnifications (If Applicable): | | |
| 1. *Continuing Review Application Submission* dates with corresponding panel action (required for approval dates issued one year ago or earlier): | | |
| 1. Summary of study materials used (for non-clinical research): | | |
| 1. List of treatments or interventions: | | |
| 1. Summary of post-trial provisions (required for clinical trials): | | |
| 1. Summary of biobanking (including total number of samples included and withdrawn): | | |
| 1. Study dose(s): | | |
| 1. Duration of the study: | | |
| 1. Study objectives and summary of results: | | |
| 1. List of informed consent form used (version/date) and attach most recent version, or report on outcome of waiver of informed consent (e.g. no follow-up of patients, anonymized data collection, and others): | | |
| 1. Report on outcome of data protection plan (e.g reports of breach of privacy, and storage of identifiable information): | | |
| **DATE OF LAST REVIEW:** <dd/mm/yyyy> | | |
| **SIGNATURE OF PI:** | | |
| **DATE SUBMITTED:** <dd/mm/yyyy> | | |
| **RECEIVED BY:** | | |

**RECOMMENDATIONS (for UPMREB use only)**

|  |  |  |  |
| --- | --- | --- | --- |
| **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study) | | | |
| **RECOMMENDED ACTION:**   * APPROVE * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |