**Early Study Termination Report Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *This form is required to apply for premature termination or suspension of a study and refers to ICH-GCP Section 4.12: PREMATURE TERMINATION OR SUSPENSION OF A TRIAL. 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***

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| --- | --- | --- |
| **UPMREB CODE:** | | |
| **STUDY PROTOCOL TITLE:** | | |
| **PRINCIPAL INVESTIGATOR:** | | |
| **INITIAL APPROVAL DATE:** | | |
| **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:** | | |
| **STUDY SITE ADDRESS** | | |
| **SPONSOR:** | | |
| **SPONSOR CONTACT PERSON:** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **REPORT SUBMISSION DATE:** (to be filled out by UPMREB) <dd/mm/yyyy> | | |
| 1. **START DATE:** | | |
| 1. **PROPOSED TERMINATION DATE:** <dd/mm/yyyy> | | |
| 1. **PARTICIPANTS ENROLLED TO DATE:** | | |
| 1. **SUMMARY OF RESULTS TO DATE:** | | |
| 1. **TERMINATION PACKAGE PROVIDED FOR SUBJECTS WHO HAVE BEEN RECRUITED:** | | |
| 1. **REASON FOR TERMINATION with JUSTIFICATION:** | | |
| **SIGNATURE OF PI:** | | |
| **DATE OF REPORT:** <dd/mm/yyyy> | | |

**RECOMMENDATIONS (for UPMREB use only)**

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| **Comments of Primary Reviewer** (i.e. implication on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants) | | | |
| **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> |