Early Study Termination Application 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. Obtain an electronic copy of this form and encode all information required in the space provided. Print the application in A4 size paper; then date and sign this form before submission. Approval of this application would require further completion of UPLB REB FORM 3(C): FINAL REPORT FORM.*

| UPLB REB CODE: |
| --- |
| STUDY PROTOCOL TITLE: |
| APPROVAL DATE: |
| PRINCIPAL INVESTIGATOR: |
| STUDY PROTOCOL APPROVAL DATE: <dd/mm/yyyy> |
| Email: | Telephone: | Mobile: |
| STUDY SITE:  |
| STUDY SITE ADDRESS |
| SPONSOR: |
| SPONSOR CONTACT PERSON: |
| Email: | Telephone: | Mobile: |
| APPLICATION SUBMISSION DATE: (to be filled out by UPLB REB) <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. REASON FOR TERMINATION with JUSTIFICATION:
 |
| SIGNATURE OF PI: |
| DATE OF APPLICATION: <dd/mm/yyyy> |

RECOMMENDATIONS (for UPLB REB use only)

| Comments of Primary Reviewer  |
| --- |
| 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> |