Please complete this form and submit to the Institutional Review Board before the due date.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Initial Approval:**  \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ | | | | **Date of Last Approval:**  \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ | **Due Date:**  \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ | | **IRB NO.**  \_\_\_\_\_\_ |
| **Progress / Continuing Report:**  ⬜ ทุก 3 เดือน ⬜ ทุก 6 เดือน ⬜ สิ้นสุดการวิจัยหรือทุก 1 ปี | | | | | | |
| **Protocol title** | | | **(ไทย)**  **(English)** | | | | **Remarks** |
| **Principal investigator:** | | | | | | |  |
| **Sponsor:** | | | | | | |  |
| **Study Code:** | | | | | | |  |
| 1. | Has the data collection begun? | | | | | Yes ⬜ |  |
| No ⬜ |
| 2. | How much data have you collected so far? ............. % | | | | | |  |
| 3. | Has data been obtained directly from human participants?  ⬜ Yes (Go to 4)  ⬜ No  Please specify type of Study  ⬜ Chart review ⬜ In vitro study  ⬜ Leftover specimen ⬜ Other………………………….  And then skip to 8 | | | | |  |  |
|  |
|  |  |
| 4. | In case of participant enrollment | | | | | |  |
|  | 4.1 | Total participants expected to be recruited **at the beginning** | | | |  |  |
|  | 4.2 | Number of participants recruited | | | |  |  |
|  | 4.3 | Number of participants expected to be recruited **from now** | | | |  |  |
|  | 4.4 | Total drop-out or loss follow-up | | | |  |  |
|  | 4.5 | Total Withdraw | | | |  |  |
|  | 4.6 | Total Death | | | |  |  |
|  | 4.7 | Total participants still active or in contact | | | |  |  |
|  | 4.8 | Total participants completed | | | |  |  |
|  | **Remark :** 4.1 = 4.2+4.3; 4.2 = 4.4+4.5+4.6+4.7+4.8 If not, give explanation in 11. | | | | | |  |
| 5. | Which procedures do active participants have to undertake? | | | | | |  |
|  | Questionnaire/interview ⬜ | | | | | |  |
|  | Specimen/sample collection ⬜ | | | | | |  |
|  | *In vivo* diagnostic devices ⬜ | | | | | |  |
|  | Interventions: e.g. drug trial, surgical procedure, radiation, isotope,… ⬜ | | | | | |  |
|  | Others (specify)…..………………………………………………………………………………….………… ⬜ | | | | | |  |
| 6. | 6.1 Have there been any SAE on site during this reported period? | | | | | Yes ⬜ | Go to 6.2 |
| No ⬜ | Go to 7 |
|  | 6.2 Have you submitted the SAE to IRB? | | | | | Yes ⬜ | Attach response document from IRB |
| No ⬜ | Attach Report |
|  | 6.3 How many total SAE have occurred? | | | | |  |  |
| 7. | 7.1 Are there changes to the protocol or consent form during this report period? | | | | | Yes ⬜ | Go to 7.2 |
| No ⬜ | Go to 8 |
| 7.2 Have you submitted the changes to IRB? | | | | | Yes ⬜ | Attach response document from IRB |
| No ⬜ | Attach Report |
| 7.3 How many total amendments have been made? | | | | |  |  |
| 8. | 8.1 Are there Deviation / Violation / Non-compliance during this report period? | | | | | Yes ⬜ | Go to 8.2 |
| No ⬜ | Go to 9 |
| 8.2 Have you submitted the Deviation / Violation / Non-compliance to IRB? | | | | | Yes ⬜ | Attach response document from IRB |
| No ⬜ | Attach Report |
| 8.3 How many total Deviation / Violation / Non-compliance have been reported? | | | | |  |  |
| 9. | Request for Certificate of Approval (COA) Renewal | | | | | Yes ⬜ |  |
| No ⬜ |  |
| 10. | Risk/Benefit ratio: Risk ⬜ increased, ⬜ same, ⬜ decreased  Benefit ⬜ increased, ⬜ same, ⬜ decreased | | | | | |  |
| 11. | Explanatory Note: (if any) | | | | | |  |
| 12. | Summary of current status:  ⬜ (A) 1) the research is permanently closed to the enrollment of new subjects; and 2) all subjects have completed all research related interventions; and 3) the research remains active only for long-term follow-up of subjects.  ⬜ (B) No subjects have been enrolled and no additional risks have been identified.  ⬜ (C) The remaining research activities are limited to data analysis.  ⬜ (D) Not (A), (B) or (C) | | | | | |  |

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| Investigator’s signature ……………....................…...…...................................... Date…….....…../…….....…./…….....…..  ……………........................…...................................................................................... (Print Name-Surname) |