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

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| --- | --- | --- | --- |
| **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)⬜ NoPlease 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) |