Instruction: Please fill in the form or tick 🗸 in the box that applied, and attach documents if necessary.

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| --- | --- | --- |
| **Protocol title (ไทย)**  **(English)** | **IRB No.** | **Remarks** |
| **Study Code** | |  |
| **Principal Investigator** | |  |
| **Sponsor** | |  |
| 1. **Which part of the study do changes apply?** (more than one is possible)   Protocol ⬜  Participant Information sheet ⬜  Consent form ⬜  Investigators ⬜  Other (specify) .................................................... ⬜ | |  |
| 1. **List all proposed change(s) and rationale for change(s) (detailed documents can be attached)** | |  |
| 1. **How will the amendment affect the risk and benefit for the participants?**   **Risk** may be ⬜ increased ⬜ same ⬜ decreased  **Potential benefit** may be ⬜ increased ⬜ same ⬜ decreased | |  |
| 1. **How does the amendment affect the informed consent?**   New consent is not required ⬜  New consent is in addition to the current one ⬜  New consent is to replace the current one ⬜ | |  |

Note: Study amendments may not be instituted until written approval from the ethics committee is received.

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