|  |  |  |
| --- | --- | --- |
|  | |  |
|  | **Uttaradit Rajabhat University**  **Research Ethics Committee** | **Submission for Study Amendment**  **แบบรายงานการแก้ไขเพิ่มเติมโครงการวิจัย** |

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

|  |  |  |
| --- | --- | --- |
| **Protocol title**: | **URU-REC. No**. | For the record only |
| **Study Code:** |
| **Principal Investigator**: | **Investigator No**. |  |
| **Sponsor**: | |  | |
| 1. **Which part of the study do changes apply?** (more than one is possible)  Protocol \_\_\_\_  consent form \_\_\_\_  investigators \_\_\_\_  Other (specify) ........................................ \_\_\_\_ | |  | |
| 2. **List all proposed change(s) and rationale for change(s) (detailed documents can be attached)** | |  | |
| 3. **How will the amendment affect the risk and benefit for the subjects**?  **Risk** may be increased same decreased  **Potential benefit** may be increased same decreased | |  | |
| 4. **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.

Investigator signature……………...…………….………………….………Date………/………/………

(Please retain copy of the completed form for your study record.)