Memorandum

Suranaree University of Technology

Institute Phone Number Fax Number \_\_\_\_\_

Document Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Re: Resubmission for Study Amendment (Code …………………………..)

To The Chair of the Human Research Ethics Committee

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institute of Resubmit for study amendment to The Human Research Ethics Committee according to the summary of changes and attach document for the committee’s consideration as follow :

1. Resubmission for study amendment (AF/01-11/01.0)
2. Summary of changes (AF/02-11/01.0)

Please kindly consider my resubmission for study amendment.

(Project Head) (your signature)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Advisor)

**AF/01-11/01.0**

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| --- | --- |
| **โลโก้มทสขาวดำ Human Research Ethics Committee Suranaree University of Technology** | **Resubmission for Study Amendment** |

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

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| --- | --- | --- |
| **Protocol title**: | **COA 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.)

**AF/02-11/01.0**

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| **โลโก้มทสขาวดำ Suranaree University of Technology**  **Institutional Ethics Committee** | **Summary of changes** |

**Protocol title** : .............................................................................................................................................

**Principal Investigator** : ..................................................................................................................

**Study Code :** .................................................... ........................................................................................

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| --- | --- | --- | --- | --- |
| No. | items | Original | New | Reasons |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |