**Memorandum**

**Suranaree University of Technology**

Institute Phone Number

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

Re: Amendment of Research Protocol Approved by Human Research Ethics Committee or Request for Endorsement of Additional Documents (EC- )

To The Chair of the Human Research Ethics Committee

I, (Name and Status) ................................................... of (office of affiliation) ..........................

would like to make an amendment / request for endorsement of additional documents for the research protocol entitled .............................................................................................. Protocol ID: EC………………, which was approved by the Ethics committee. I have enclosed the following documents for your considerations:

1. One copy of Protocol Amendment Report Form/Request for Endorsement of additional documents

2. One copy of the list of presently used documents (Indicate issue no. and date)

3. One copy of documents to be amended/endorsed (Indicate issue no. and date)

4. Evidence of fee payment (for protocol sponsored by external sources only) (if any)

Thank you for your kind considerations.

|  |  |
| --- | --- |
| Signed………………………………….… | Signed………………………………….… |
| (……………………….…………) | (………………….……………) |
| Research Advisor in case the principal investigator is a student | Principle Investigator |

**AF/01/11/02.0**

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| --- | --- | --- |
| **โลโก้มทสขาวดำ Human Research Ethics Committee Suranaree University of Technology** | | **Report for Protocol Amendment or Request for Endorsement of Additional Document** |
| **Protocol title**: | **COA No**. | |
| **Protocol ID:** | **approved on:** | |
| **Name of Principal Investigator**: | **Office of Affiliation:** | |
| **Mobile Phone No.:** | **e-mail:** | |
| **Sponsor**: |  | |

**Please check the topics to be amended.**

* Change in Principal Investigator or research team (Please indicate reasons for the change and attach a letter of acceptance including CV and works of the new PI or team member.
* Change in research site from ................................................................ to ..........................................................

(Please give reasons for the change and attach details of suitability of the new site)

* Change in volunteer number from ……… to ............. (Please give reasons and calculation formula)
* Change in research procedure (Please give details, reasons for the change, and amended research documents)
* Change in Investigator Brochure from issue number …………… to ………………….. (Please give details and reasons for the change, and attach the new document)
* Change in Information Sheet and Informed Consent (Please give details and reasons for the change, and attach the amended documents)
* Other changes. Please specify ............................................................................
* Request for endorsement of additional documents. Please specify .....................................................................
* Request for minor changes which are
* changes in spelling, date, issue number, and format of the research proposal, or documents related to Investigator’s Brochure (Please give details and reasons for the amendment, and attach the new document)
* changes in research coordinator that is not stated in the Information Sheet (Please give details)
* statements in advertised volunteer invitations (Please give details and reasons for the change, and attach the new documents)
* contracts, material transfer agreements (Please give details and reasons for the change and attach the new documents)

I’d like to report the present status of the research protocol as follow:

1. Research operation at research site

□ The research has not started.

□ The research has started and this is the first report. One copy each of Information Sheet and Consent formed signed by the first volunteer, both documents are verified for true copies.

□ The research has started and the last progress report was made on (date) ..................

1. Data relating to protocol’s subjects or samples from the beginning of the protocol to the date of this report. Please fill in the blanks related to the data studied.

| **For protocols with subject recruitment** | **For protocols that study existing data** | **For protocols that study samples /biological samples** |
| --- | --- | --- |

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| --- | --- | --- |
| * 1. Number of subjects required: .........   2. Total subjects consented: .........,   which is …………% of total number of subjects planned for the research protocol   * 1. Number of screening failure subjects: .........   2. Number of withdrawn subjects: .........   3. Number of subjects who died from the onset of the research protocol: ........, and number of those who died during this report period: .......   2.6 Number of active subjects: .........  2.7 Number of subjects in follow-up: .........  2.8 Number of completed or inactive subjects (excluding those from 2.3 to 2.7): ......... | * 1. Number of cases required: ........., or data collection period from ............... to ...................   2. Number of cases collected: ............, which is …………% of the total number of cases planned for the research protocol   3. Number of completed cases: ......... | 2.1 Number of biological samples required: .........   * 1. Number of biological sampled collected: ........., which is …………% of the total umber of samples planned for the research protocol   2. Number of completed biological samples: ......... |
|  |  |  |

* Please fill in details in case your protocol does not fit in categories 2.1 to 2.8 .................................................................................

I certify that I have checked the correctness of the information and that I have truthfully completed this report.

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| Signed ................................................ |
| (..........................................................) |
| Principal Investigator |
| Date............................................................... |

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

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

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

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