**Memorandum**

**Suranaree University of Technology**

Institute Phone Number

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

Re: Closing report for protocol approved by Human Research Ethic Committee (EC- )

To The Chair of the Human Research Ethics Committee

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

would like to request for Closing report for protocol approved by Human Research Ethic Committee protocol entitled: ...............................................................................................,

Protocol ID: EC-………………, which was approved by the Ethics committee. I have enclosed the following documents for your considerations:

1. One set of summary of the research findings to inform HREC-SUT of the protocol closing (AF/01-13/02.0)

2. One set of summary or abstract of the study

Thank you for your kind considerations

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

**AF/01-13/02.0**

|  |  |
| --- | --- |
| **โลโก้มทสขาวดำ Human Research Ethics Committee Suranaree University of Technology** | **Study Report Form (Final Report)** |

**Please attach the Executive Summary or Abstract of the study with this report**

|  |  |
| --- | --- |
| Protocol ID.: | Code of Approval (CoA. No.) |
| Date of approval :  |
| Protocol title: |
| Principle Investigator: |  |
| Phone  | E-mail: |
| Sponsor’s Name |  |
| Address: |  |
| Phone  | E-mail: |

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** |
| * 1. Number of subjects required: .........
	2. Total subjects consented: ........., which is ……% of total number of subjects planned for the research protocol
	3. Number of screening failure subjects: .........
	4. Number of withdrawn subjects: .....
	5. Number of subjects who died from the onset of the research protocol: ........, and number of those who died during this report period: .......
	6. Number of active subjects: .........
	7. Number of subjects in follow-up: .........
	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: .........
 | * 1. Number of biological samples required: .........
	2. Number of biological sampled collected: ........., which is …………% of the total number of samples planned for the research protocol
	3. Number of completed biological samples: .........
 |

* Please fill in details in case your protocol does not fit in categories 2.1 to 2.8 ...................
1. Data related to adverse events that happened at your research site:
	1. Number of serious adverse events or unexpected adverse events: ............................

(Serious adverse events refer to adverse events that happened to the subjects and could cause death, disability, hospitalization, or prolonged hospitalization to the subjects. Unexpected adverse events refer to subjects’ illnesses that are not listed as side effects in the research protocol or investigator’s brochure.)

1. Are there any unexpected or unanticipated problems at your research site? (Unexpected events refer to any events that are not listed as serious adverse events or unexpected serious events, but the researcher considers that they may be problematic to the research protocol, for example, fire at the research site, relocation of the research site, research assistants indicted, etc., or that they may affect data storage such as damages to the data storage computer, or data robbery, etc.)

🞎 No 🞎 Yes. Please give details and number of problems: …………… (If you have not reported the problems before, please attach a report of the incidents).

1. Data related to protocol operation

3.1 Are there any protocol violations that you have not reported to the committee?

🞎 No 🞎 Yes

3.2 Are there any protocol deviations that you have not reported to the committee?

🞎 No 🞎 Yes.

4. Are there any changes in the people responsible for the research protocol that you have not reported to the Ethics Committee?

🞎 No 🞎 **Yes. Please attach a report.**

5. Are there any changes in the research protocol documents that you have not reported to the Ethics Committee?

🞎 No 🞎 **Yes. Please attach a** **report.**

6. Are there any subjects’ complaints related to your research protocol during this report period?

🞎 No 🞎 **Yes. Please specify or attach a report.**

7. Summary of initial report (as per research objectives) ........................................................................................................................

 ........................................................................................................................................

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

|  |
| --- |
|  Signed........................................................ |
| (..........................................................) |
| Principal Investigator |

 Date ……… /……… /………

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

Reviewer Comments:

( ) Date:………………….…………

 Reviewer’s signature