**Memorandum**

**Suranaree University of Technology**

Institute Phone Number

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

Re: Progress report for research protocol approved by 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 a renewal of and to submit a progress report for the research protocol....................................................................................................................................................,

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

1. One copy of HREC-SUT Protocol Renewal Form

2. One copy of other related documents

3. One copy of the list of the latest documents used at present (please indicate number and date of issue)

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

5. List of participants' hospital number (HN) for clinical trials conducted in patients of Suranaree University of Technology Hospital. (if any)

Thank you for your kind considerations

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

**AF/02-12/02.0**

|  |  |
| --- | --- |
| **โลโก้มทสขาวดำ Human Research Ethics Committee Suranaree University of Technology** | **Protocol Renewal and Progress Report Form** |

|  |  |
| --- | --- |
| Protocol ID.: | COA. No. |
| Protocol title: |  |
| Principal Investigator:  |  |
| Mobile Phone No.:  | e-mail:  |
| Office of Affiliation:  |  |
| Sponsor:  |  |

**Details:**

1. Is this the first report after volunteer recruitment?

🞎 No

🞎 Yes. Please attach a copy of Information Sheet and Informed Consent Form signed by the first volunteer, which are verified as true copies by the researcher.

1. Have you started collecting data at your research site?

🞎 Yes 🞎 No. Please skip to no. 5.

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** |
| * 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: .......

3.6 Number of active subjects: ......... 3.7 Number of subjects in follow-up: ......... 3.8 Number of completed or inactive subjects (excluding those from 3.3 to 3.7): ......... | * 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 umber 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 3.1 to 3.8.........................
1. Data related to serious adverse events or suspected unexpected serious adverse reactions (SUSARs) and unanticipated problems that happened at your research site:
	1. Are there any serious adverse events or suspected unexpected serious adverse reactions (SUSARs) that you have not reported to the Ethics Committee?

🞎 No 🞎 Yes. Please attach the SAE in-site report form.

(Serious adverse events refer to adverse events that happened to the subject and could cause death, disability, hospitalization, or prolonged hospitalization to the subjects. Unexpected serious 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 events that you have not reported to the Ethics committee?

🞎 No 🞎 Yes. Please attach the SAE in-site report form.

(Unexpected events refer to any events that are not listed as serious adverse events or unexpected events, but the researcher consider 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.)

1. Data related to the protocol operation
	1. Are there any protocol violations that you have not reported to the Ethic Committee?

🞎 No 🞎 Yes. Please attach the report form.

* 1. Are there any protocol deviations that you have not reported to the Ethic Committee?

🞎 No 🞎 Yes. Please attach the report form.

* 1. 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 the** report form and CV of the new responsible person.

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

🞎 No 🞎 **Yes. Please attach the report form.**

7. Are there any changes in new knowledge related to the operation of this research protocol?

🞎 No 🞎 **Yes. Please attach the report form.**

8. Are there any additional data related to risks and benefits of the research protocol?

🞎 No 🞎 **Yes. Please attach the report form.**

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

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

10. During this report period, is there any news related to your research protocol that may affect the people’s attitude or their decision to join your research protocol?

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

11. Problems and obstacles that prevent research operations: ………………………………………….

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

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

Reviewer Comments:

 ( ) Date:………………….…………

 Reviewer’s signature