 **Memorandum**

**Department..........................................................................Phone..................................**

**Ref.…….........……/.............................. Date....................................................................**

**Subject** Report Progression to the Ethics Committees

**To** Chair of the Center for Social and Behavioral Sciences Institutional Review Board, Prince of Songkla University

I, ..............................................................affiliated with...........................................................

would like report the progression of my project (name in Thai and English)

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 Project code............………………, Latest certification date………………………..……, and attached documents for consideration as follows:

|  |  |  |
| --- | --- | --- |
| Attachment list | Copies(amount) | Inspector |
| Pass | Edit |
| 1. AP-007 Progress Report Form
 | 3 |  |  |
| 1. A copy of the statement and a copy of the consent form of the first volunteer (in the case of the first progress report) or the latest volunteer (in the case of the second progress report onwards).
 | 3 |  |  |
| 1. Fees payment form and proof of payment.
 | 1 |  |  |
| 1. Other related documents (as stated by the researchers in the progress report form).
 | 3 |  |  |
| 1. All CD/DVD or electronic files containing information accordingly to items 1 – 4, 1 CD/file.
 | 1 |  |  |
| Sign………………………………….…… | Sign………………………………….… |
|  (………………..…………………) | (…………………….…………) |
|  Advisor (In case the project leader is a student) |  Research project leader |
|  Sign…………………………………. |
| (…………………….……………) |
| Position....................................................Head of the affiliation |

For officers

Dear researchers; the following are incomplete document(s): ………………………………………………………………………………………

I will be able to proceed with the further steps once the complete documents have been received. Signed……………………………..…….Date ………………….……

|  |
| --- |
| **Research Progress Report Form****Submission Form for Progress Report** |
| Project code: | PROTOCOL No. (sponsored):  |
| Project name (Thai):  |
| Title (ENG): |
| Project leader:  | Affiliation: |
| Funding source: |
| Operating period approved by SBSIRB-PSU (According to the research project) from\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| SBSIRB-PSU first approval date \_\_\_\_\_/\_\_\_\_/\_\_\_\_\_ (term ..........................) SBSIRB-PSU latest renewal approval date: \_\_\_\_\_/\_\_\_/\_\_\_\_\_Required to renew every\_\_\_\_\_\_ months and are scheduled to report on progress every\_\_\_\_\_ months**certification expiration date \_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_** |
| **Report times\_\_\_\_\_ Operation during: Date\_from\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_to\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** This report is 🞏.......................months progress report  |
| Document submission 🞏 submitted on time 🞏submitted after the submission deadline but time has not expired 🞏 submitted after the expired date \*\* |
| **Trial Progress** | 🞏 The projects don't relate to direct interaction with volunteers, such as retrospective review, left over, and secondary data analysis (skip to item 3). Please specify………………………………………………… | **Note (if any)** |
| 1. **Number of volunteers (since the beginning of the project)** |
| 1. Total sample size approved by SBSIRB-PSU
 |  |
| 1. Total subject consented
 |  |
| 1. Number of screening failures
 |  |
| 1. Number of people still in the intervention phase

(active subjects)  |  |
| 1. Number of people in the follow-up phase

(inactive subjects) |  |
| 1. Number of people who withdrew

(including withdrawal/death) |  |
| 1. Number of people who completed the entire process (completed)
 |  |
| 2. Are there any volunteers who withdrew or are withdrawing from the project since the authorized date or latest renewal by SBSIRB-PSU? If so, please provide brief details. | 🞏 yes | 🞏 no🞏 not relevant |
| **Protocol related documents** | 3. Since the last renewal approval date, are there any changes in the protocol and relevant documents? If so, please summarize and attach supporting evidence, such as an amendment certificate from SBSIRB-PSU. | 🞏 yes | 🞏 no |
| 4. Since the last renewal approval date, are there any changes in the Investigator’s Brochure? If so, please summarize and attach supporting evidence, such as an amendment certificate from SBSIRB-PSU.  | 🞏 yes | 🞏 no🞏 not relevant |
| 5. Since the last renewal approval date, is there additional new information about the risks involved in the research? If so, please summarize and attach related documents. | 🞏 yes | 🞏 no |
| **Risk & Benefit** | 6. Since the last renewal approval date, are there any unanticipated research-related problems that affect the risk to the volunteers? If so, please summarize and attach supporting documents. | 🞏 yes | 🞏 no |
| 7. Since the last renewal approval date, are there any changes in the risk: benefit ratio? If so, please explain, | 🞏 yes | 🞏 no |
| **Informed consent** | 8. Since the last renewal approval date, are there any changes in the informed consent document? If so, please summarize and attach the latest notification document. | 🞏 yes | 🞏 no🞏 not relevant |
| 9. Since the last renewal approval date, is there a problem with the consent request process? If so, please summarize. | 🞏 yes | 🞏 no🞏 not relevant |
| **Local issues** | 10. Since the last renewal approval date, are there any complaints about the research project from the volunteers? If so, please summarize the incident, assessment, and resolution. | 🞏 yes | 🞏 no🞏 not relevant |
| 11. Since the last renewal approval date, are there any negative effects on the relevant communities from the project? If so, please summarize. | 🞏 yes | 🞏 no |
| **Investigators** | 12. Since the last renewal approval date, are there any changes in the research team? If so, please attach relevant documents, such as an amendment certificate from SBSIRB-PSU. | 🞏 yes | 🞏 no |
| 13. Since the last renewal approval date, are there any change in the status or affiliation of the researcher? If so, please summarize and attach the relevant documents. *(CV)* | 🞏 yes | 🞏 no |
| **Other issues** | 14. Since the last renewal approval date, are there any investigator's concerns about conducting research at the research site? If so, please summarize the research's concerns. | 🞏 yes | 🞏 no |
| 15. Since the last renewal approval date, there is information from the visit summary report of the Visiting Sub-Committee. If so, please summarize and attach related documents. | 🞏 yes | 🞏 no🞏 not relevant |
| 16. Past performance (In summary, about 0.5 - 1 A4 pages) |
| 17. Action plan for the next phase |
| 18. Explanation of problems, obstacles (if any), and solutions to ensure the work can be completed as scheduled. |

I hereby certify that the above statements are true and understand the meaning clearly in all respects.

|  |  |
| --- | --- |
| Signed…………………………..………. |  Signed……………………….……………. |
|   (……………………………...….……)Advisor(In case the project leader is a student) | (…….………….…………………….……)Research project leader |
| Date ………………………………… | Date ……………………………..………….. |