Instruction for the Investigator of the Projects Received Ethical Approval for Human Research Center for Social and Behavioral Sciences Institutional Review Board, Prince of Songkla University

**** Important ****

Please check the accuracy of the certificate of ethical approval, the progress report period, and the expiration date of your project. In general, the research project will not be approved no longer than one year. If the investigator needs to renew the certificate of ethical approval, please process the certificate at least 30 days before the expiration date.
The investigators cannot recruit new volunteers during the research project's expiration, and any data collection during the expiration period may not be allowed for analysis.

After the Institutional Review Board (IRB) approval, the investigator has responsibilities as below;

1. The investigator must conduct the research in strict accordance with the current IRB-approved research project using the information sheet, the consent form, and other documents that have been approved by the Ethics Committee. (There must be a stamp from the Office of the Ethics Committee)

2. The investigator is required to report to the Ethics committee as below;

2.1 Progress Report and/or Renewal

Progress report to the Ethics Committee or progress report with renewal upon completion of the period specified in the certification of ethical approval as explained below;

- In case of a progress report (Not yet due for renewal), please submit the Submission Form for Progress Report (AP-007) to Ethics Committee at least 30 days before the expiration date.
- In case of a progress report with renewal, please submit the Submission Form for Progress Report (AP-007) and the Amendment Form (AP-005) at least 30 days before the expiration date. The investigator cannot recruit new volunteers during the research project's expiration, and the data collected during the expiration period may not be allowed for analysis.

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2.2 Protocol amendment

The request for the protocol amendment, for example, changing the research team, the research methods, or adding other documents, please submit the Submission Form for Amendment (AP-005) and clearly state what changes have been made, how, and reason for the changes. In case of a change in the principal investigator/co-investigator, a CV must be attached.

2.3 Report of Serious adverse events that occur with volunteers (either related to the research process or not)

The investigator must initially report to the Ethics Committee within 7 days and send the completed information within 15 days after the investigator notices the incident **(In case of volunteer's death, an initial notification must be made to the Ethics Committee within 24 hours.)** by submitting the **Serious Adverse Event Report Form (AP-006)** via Email address: sbsirb.hatyai!@gmail.com or contact during an office hour at Tel. 0-7428-6470 and Fax. 0-7428-6421.

2.4 Non-compliance/deviation report

After conducting the research, if any actions are not complied with the approved research project or research methodology (deviation) or do not report progress or renew as required (non-compliance), the investigator must report any non-compliance to the Ethics Committee within 7 days of the occurrence by submitting the **Deviation/Non-compliance Report Form (AP-009)**. Also, the investigator must propose concrete guidelines to prevent the recurrence.

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2.5 Final report

Upon completion of the research process as scheduled, the investigator must notify the closure project and attach the research result to the Ethics Committee by submitting a **Final Report Form (AP-010).** If it is necessary to terminate the project, please submit the Termination **Report Form (AP-011)**.

3. The Ethics Committee will randomly site visit the research project to ensure adherence to the protocol, listen and give advice on any problems that may arise during conducting the research. The Office of the Ethics Committee will provide a written notice 14 business days in advance. The results of the site visit will be reported to the Ethics Committee meeting and informed the investigator, and there may provide recommendations for further process.

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