Guidelines for Investigators
In Projects with Human Research Ethical Approval
Human Research Ethics Committee, Faculty of Medicine, Prince of Songkla University

**** Important ****

Please check the validity of the Certificate of Approval
And check your project's Progress Report Period and Expiration Date
Generally, the Committee will approve a project for no more than 1 year, and the investigator must extend the project at least once per year
Investigators are not allowed to recruit new participants while the project is expired
Analysis of data collected while a project is expired is prohibited

After a project receives ethical approval, investigators have the following duties and responsibilities

1. Investigators must strictly follow the procedures written in the Protocol document, using ONLY the Participant Information Sheet, Informed Consent Form, and other documents that were approved by the Committee (the documents must contain a seal of approval from the Human Research Ethics Committee)

2. Investigators are required to make the following reports to the Ethics Committee:

2.1 Progress report or extension report

2.1.1 Progress report (or progress report with extension), made to the Ethics Committee when the project has proceeded to the end of the designated period, as stated in the ethical approval certificate

- In case of progress report (the extension period has not arrived), file **the Progress Report Form for the Human Research Ethics Committee (AP-014)** at least 30 days prior to the due date

- To report progress with extension, file the AP-014 form at least 60 days in advance. Investigators cannot accept new participants while the project is expired, and analysis of data collected while the project is expired may be prohibited

2.1.2 To report progress to the Funding Committee, submit another set of report to the funding committee, namely, **Progress Report Form for the Faculty of Medicine Research Funding Committee (RES-PR1)**

2.2 Protocol Amendment

If an investigator wishes to make an amendment to the protocol, e.g., changing team members, changing the research methodology, or add documents, make such proposals with the **Protocol Amendment Form (AP-016)**, listing the requested changes and the reasons. In case of changes to the Principal Investigator or addition of new investigators, please attach their resumes.

2.3 Report of serious adverse events among participants at the study site (regardless of relation to the study procedures)

The investigator must file an initial report to the Ethics Committee within 7 calendar days and send all detailed information with 15 calendar days (in case that a participant dies, an initial report must be made within 24 hours after an investigator is informed, via electronic mail). Use the **Initial Report Form for Severe Adverse Event at Study Site (AP-017).**

2.4 Non-compliance/deviation report

After a study begins, when there is any action that does not follow the approved protocol or methodology (deviation), or when progress reports or extensions are not made according to schedule (non-compliance), the investigator must report non-compliance or deviation to the Committee within 7 calendar days after noticing the problem using the **Non-Compliance or Deviation Report Form (AP-019)**. The investigator is also required to present practical guidelines to prevent the issue from recurring.

2.5 Final Report

When the study procedures are completed, the investigator is to issue a closing report with the study results for the Committee's information, using the **Project Closing Report Form (AP-020)**. In case of early termination, report with the **Early Termination Report Form (AP-021)**.

3. The Committee will make random site visits to check the progress of each project, and to note and give advice on issues that may arise during the site visit. The Committee will issue a 2-weeks advance notice, and the visit's findings will be shared for information at a Committee Meeting and subsequently notify the Investigator, potentially with recommendations for actions.