



Researcher's Guidelines  
for project approved by  
the PSU HREC

**\*\* IMPORTANT \*\***

Examine accuracy of the certificate of approval,  
discern timeline for progress reports and project's deadline.

Approvals received from the Ethics Committee generally may not exceed 1 year.

Request for an extension must be submitted at least 30 days prior to the deadline.

During the period where a project is expired, no new volunteers may be recruited. Any data collected during such time is not allowed to be analyzed.

Once an ethical approval is received, the researchers have the following duties and responsibilities:

1. The researchers must strictly adhere to the procedures as stated in the project statement, informed consents, or other relevant documents that have been approved and stamped by the HREC.
2. The researchers must report the following to the the PSU Human Research Ethics Committee, Prince of Songkla University
  - 2.1 **Progress reports and/or extensions**

**Procedures of submitting progress report or progress report with an extension request** once the project reaches the end of approved period

    - Progress report submission (no extension): Submit Progress Report Form ([AP-007](#)) to the HREC at least 30 days before the expiration date
    - Progress report submission (with extension): Submit Progress Report Form ([AP-007](#)) along with Protocol Amendment Form ([AP-008](#)) at least 30 days before the expiration date. During the time when a project is expired, no new volunteers may be recruited and data collected is not allowed to be analyzed.
  - 2.2 **Protocol amendment form**

A request for protocol amendment such as change in research team members, modification of methodology or adding documents must be submitted by using the Protocol Amendment Form ([AP-008](#)). All of the changes and reasons must be clearly indicated. The principal investigator/co-investigator must also enclose biography.
  - 2.3 **Reporting serious adverse events experienced by the volunteers (whether related to the research process or not)**

Researches must submit a preliminary report to the HREC within 7 days of discovery, followed by a full-detailed report within 15 days (Report of death must be submitted

within 24 hours Email: arunwan.s@psu.ac.th or call 074-286955 fax: 074-286961 during office hours) by using the **Serious Adverse Event Form** [\(AP-009\)](#)

**2.4 Non-compliance/deviation report**

Report of any deviation or non-compliance must be reported to the HREC within 7 days from date of discovery, by submitting **Non-compliance/deviation Form** [\(AP-011\)](#) and include a concrete proposal to prevent the problem in the future.

**2.5 Final report**

Upon study completion, researchers must submit **Final Report Form** [\(AP-012\)](#). When a termination (before completion of the study) is warranted, the **Termination Form** [\(AP-013\)](#) must be submitted.

3. The HREC conducts random research site visits to observe the conduct of each project, and also to provide the opportunity to listen in and give advice. The HREC shall issue a notice 14 days prior to the visit. The result of such a visit shall be reported to the Ethical Committee meeting as well as to the research team in hope to provide further guidance of each project.