Guidelines for Researchers whose Research Project has been approved by Human Research Ethics Committee, University of the Thai Chamber of Commerce

1. Researchers must strictly follow the research procedures outlined in the research proposal. The research must be conducted using only the Informed Information Sheet, Informed Consent Form, publicity materials, and other related documents that have been approved by the Human Research Ethics Committee and bear its official seal of approval.

2. Researchers are responsible for reporting to the Human Research Ethics Committee in the following cases:

2.1 When the research project reaches a specified duration, researchers must submit a progress report according to the timeline set by the Human Research Ethics Committee as stated in the certificate of approval or within one year from the date specified in the certificate.

- The required documents consist of EC15_Progress Report Form and EC16_Progress Report Form

2.2 If the research project is still ongoing but the certificate of approval is about to expire, the researcher must submit a request for renewal at least 30 days before the expiration date, along with a progress report. The Human Research Ethics Committee will not approve any research activities or data collection conducted after the certificate has expired if the researcher has not applied for an extension.

2.3 If the researcher would like to modify, update, or amend the research project, change the principal investigator, or add new co-researchers, they must temporarily suspend activities involving participants/volunteers. The researcher must submit a modification request using the Protocol Amendment Report, clearly specifying what changes are being made, how they are being implemented, and the reasons for the modifications.

- The required documents consist of EC13_Protocol Amendment Form and EC14_Protocol Amendment Form

In cases where there is a change in the principal investigator, a change in co-researchers, or the addition of new co-researchers, the researcher submitting the amendment request must attach a researcher's CV and a certificate of completion for the Good Clinical Practice (GCP) training course and/or the Human Subject Protection course and/or the Fundamental Principles of Human Research Ethics course. The researcher may proceed with the study only after the Human Research Ethics Committee has approved the amendments to the research project.

Additionally, the researcher must obtain consent from participants/volunteers whenever the amendments have a direct impact.

2.4 In the event of an adverse event occurring in research participants/volunteers, the researcher must submit a report to the Human Research Ethics Committee within 7 days. If the adverse event results in the death of a research participant/volunteer, the researcher must report it to the Human Research Ethics Committee within 24 hours of becoming aware of the incident, using the Adverse Event Report form.

- The required documents consist of EC19_AE-Report Form and EC20_AE-Report Form

2.5 In the event of non-compliance or protocol deviation, the researcher must report it to the Human Research Ethics Committee within 7 days from the date of detection, using the Protocol Deviation Report form.

- The required documents consist of EC17 Protocol Deviation Form and EC18 Protocol Deviation Form

2.6 If the researcher terminates the research project prematurely, a notification letter stating the reason for termination must be submitted along with a report on the early termination of the research project and the procedures for handling research participants/volunteers after termination to the Human Research Ethics Committee.

- The required documents consist of EC21 Protocol Termination Form and EC22 Protocol Termination Form

2.7 Upon completion of the research project, the researcher must submit a final research summary report within one month after the study's completion.

- The required documents consist of EC23_Final Report Form and EC24 Final Report Form

The Human Research Ethics Committee may conduct site monitoring visits to assess the research project's compliance, address any issues, and provide guidance. The Office of the Human Research Ethics Committee will notify the researcher at least one week in advance. The findings from the site visit will be presented at the committee meeting, and the Office of the Human Research Ethics Committee will inform the researcher of the committee's decision. Recommendations for further actions may also be provided to ensure the proper conduct of the research project.

Researchers can download the required documents for Human Research Ethics review from the Office of the Human Research Ethics Committee, University of the Thai Chamber of Commerce (UTCC) website at www.utccec.com For further information, researchers may refer to the Standard Operating Procedures (SOPs) for Human Research Ethics at UTCC or contact the Office of the Human Research Ethics Committee, located on the 5th floor of Building 10, Academic Affairs Division, University of the Thai Chamber of Commerce, Tel: 02-697-6866