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

1. The researcher must strictly follow the research protocol written in the research proposal. Only the Participant Information Sheet, Consent Form, Public Relations signs, as well as other documents that have been approved and stamped by the Committee can be used.

2. It is the researcher's responsibility to inform the Committee when:

2.1 it is time to make a progress report according to the date/month/year stated by the Committee in the Research Ethics Certificate, or it has been one year from the date/month/year stated in the Research Project Certificate. The Research Project Progress Report shall be used;

2.2 the Research Ethics Certificate is expired before completion of the research project. The researcher must submit a Research Ethics Certificate Renewal Form and a Progress Report within 30 days prior the expiry date written in the Certificate, otherwise the research procedure or data collection conducted after the expiry date of the Certificate shall not be certified by the Committee;

2.3 the researcher needs to adjust, revise, amend the research project, or there is a change in the principal investigator/co-investigator, etc. the researcher must stop conducting research with participants. Then the researcher must submit a research project amendment form in which clear description must be given regarding what changes have been made, how, and reason of these changes.

In the case of change of the principal investigator or add of a co-investigator, their curriculum vitae and the Good Clinical Practice, and/or Human Subject Protection, and/or Human Research Ethics Certificates must be submitted. Only after an approval that the researcher is able to continue the research project.

However, participant consent must be granted every time that the participants are affected by the change;

2.4 adverse events occur in participants during participation in the research. The researcher must submit an Adverse Event Report Form to the Committee within 7 calendar days. Should the adverse event contribute to death of participants, the researcher must submit an Adverse Event Report Form to the Committee within 24 hours after the researcher has been informed about the event;

2.5 there is any non-compliance/protocol deviation. The researcher must submit a Non-compliance Report Form to the Committee within 7 days after the issue has been found;

2.6 protocol termination occurs. The researcher must submit a Protocol Termination Report Form in which reason(s) for the termination and measure(s) to look after participants after the termination to the Committee; and

2.7 the research project has been completed. The researcher shall submit the Final Report Form to the Committee within one month after the completion of the research project.

The Human Research Ethics Committee may make a Site Monitoring Visit at random. It is aimed at monitoring appropriate conduct of the research project and listening and providing solution to any issues occurring during the research. The Committee will inform the researcher about the visit by a written document at least one week in advance. Results of the visit will be presented before the Committee and the Human Research Ethics Committee Office will inform the researcher about the result as well as any advice for the researcher to follow.

The researcher can download relevant documents from the website of the Research Support Office. Should the researcher have any queries, please consult the Standard of Procedures (SOPs) for further information. Alternatively, please contact the Human Research Ethics Committee Office, the Research Support Office, 6th floor, Bldg. 21, telephone numbers 02 697 6380-82.