

## Protocol Deviation/ Protocol Violation/ Non-compliance Report

Title of Research Project (in Thai).....

Title of Research Project (in English).....

Code of Research Project.....

Name of Principal Investigator.....

Current Status  An academic member of University of the Thai Chamber of Commerce  
 A student at University of the Thai Chamber of Commerce  
 An outsider

Position  Lecture; specify the academic position.....  
 Staff; specify the position.....  
 Student  Bachelor's degree  Master's degree  Ph.D.

Advisor.....

School/Office.....

Type of deviation:  
 Protocol Violation  Protocol Deviation  Non-compliance

Date of event.....

Date of event became known to investigator.....

Date of form completed.....

### **Type of Protocol Deviation/Violation**

ID of participant with deviation..... The occurred event was:

- Randomisation of ineligible participant
- Eligibility criteria exception
- Incorrect number of participants
- Screening procedure required by protocol not done
- Screening or on-study procedure/lab done outside the protocol required time
- Incorrect therapy given to patient
- Visit non-compliance
- Others.....

### **Type of Non-compliance**

- Conduct of research prior to the Committee approval
- Use of documentation not yet being approved by the Committee

- Progress report specified by the Committee not done
- Recruit of new participants
- Conduct of research after the expiry date of the Certificate of Approval
- Others.....

**Notes:**

\* Protocol Deviation is conduct of research that deviates from the approved protocol's procedures in which it results in minor damage to participants or research results.

\* Protocol Violation is conduct of research that great errors or intended violation, deviation, or negligence in following the approved protocol's procedures are made in which it results in serious damage to participants or research results.

\* Non-compliance is a failure to comply with the International Conference on Harmonisation Good Clinical Practice (ICHGCP) or the Human Research Ethics Committee stipulation.

**Type(s) of deviation**.....  
 .....  
 .....

**Reason(s) of deviation**.....  
 .....  
 .....

**Impact(s) of deviation on participants**.....  
 .....  
 .....

**Correction(s) of deviation**

With participants after the event

- Discontinuing the research project by
  - Terminating the research project
  - Amending the protocol's procedures in which a request for the Committee

Review is submitted on.....

Continuing the research project by

Not amending the protocol's procedures

Adding preventive measure(s) in which a request for the Committee Review is submitted on.....

Amending the protocol's procedures in which a request for the Committee Review is submitted on.....

Others (Please specify).....

Signature.....

(.....)

Principal Investigator

Date...../...../.....