**Protocol Deviation Report**

| **Date** | **Issues stipulated in the protocol** | **Describe the deviation** | **The cause(s) that lead to the deviation** | **Corrective action plan to prevent any further deviation** | **The effect on research participants.** | **Implementation of the research participants after the event occurs.** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | ❒ Do not cause adverse events.  ❒ Causing adverse event, please specify .......................................................................  ❒ The participants had already received appropriate care  ❒ The adverse event which had not resolved (specify) ....................................... | ❒ Withdraw the affected participant(s) from the study.  ❒ Plan to conduct research after deviation  ❒ Continue the previous procedure(s) without any amendment  ❒ Amend the protocol or change monitoring (specify) .............................. |
|  |  |  |  |  |  |  |

**Does this deviation have any effect to the whole study?**  ☑ NO❒ Yes (specify) ......................................................................................................................................................................................................

Approval from thesis advisor in case of PI is a graduate student.

Signature............................................................... Advisor

(.....................................................................)

Date……………../………………../………………

Signature.........................................................................

(......................................................................)

(Principal Investigator)

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