**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

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

Signature......................................................................... Principal Investigator

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

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