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| **Ethics Review Committee**  SIDCER(Strategic Initiative for Developing Capacity in Ethical Review)recognized ERC  **Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka**  **FWA00013225**  **Reporting form for deviation and violation** | | | | | | | | |
|  | | | | | | | | |
| **ERC reference No:** |  | | | | | | | |
| **Study title** |  | | | | | | | |
| **Name of the PI** |  | | | | | | | |
| **Site** |  | | | | | | | |
| **Deviation** |  | | **Violation** | | | |  | |
| **Nature :** | **Minor** |  | | | **Major** | | |  |
| **Date of occurrence** |  | | **Number of similar events occurred during same trail** | | | |  | |
| **Patient ID** |  | | | | | | | |
| **Details of the violation/deviation** |  | | | | | | | |
| **Action taken by the PI/Co-PI** |  | | | | | | | |
| **Impact on the trial subjects** |  | | | | | | | |
| **Name:** |  | | | | | | | |
| **Signature:** |  | | | **Date:** | |  | | |