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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** |
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| **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:** |  |