**Yenepoya Ethics Committee-1**

**Ann02/SOP11/v4: Protocol Deviation / Violation Detailed Report**

**(To be filled by the Principal Investigator)**

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| 1. | YEC-1 Protocol no.: |  |
| 2.  | Protocol deviation/ violation No: (please fill one form for each deviation/violation) |  |
| 3.  | Study Title:  |  |
| 4.  | Principal Investigator: |  |
| 5.  | Department: |  |
| 6.  |  Protocol Deviationχ  Protocol Violationχ |  |
| 7.  | Initial report by: |  |
| 8.  | Date of initial report:  |  |
| 9. | Reported to YEC-1 by: |  |
| 10.  | Description of deviation (s)/violation(s):  |  |
| 11.  | Reason (s) for the protocol deviation/violation: |  |
| 12.  | Number of participants/samples affected:  |  |
| 13. | Corrective action already taken:  |  |
| 14. | Corrective action planned:  |  |
| 15. | Number of deviations/violations previously reported with dates  |  |
| 16. | Whether corrective action taken for the same |  |
| 17. | Signature with date:  |  |