**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: |  |