# ANNEX 1

**AF/01-016/01**

**Deviation / Non-Compliance / Violation Record**

|  |  |  |
| --- | --- | --- |
| Protocol Number: | | Date:…………………… |
| Study Title: |  | |
| Investigator | | Contact No.: |
| Institution: | | Contact No.: |
| Sponsor: | | Contact No.: |

|  |  |
| --- | --- |
| ⬜ Deviation from protocol | ⬜ Non-Compliance |
| ⭘ Major ⭘ Minor | ⬜ Violation |
| Description: |  |
| IRB’s Decision: |  |
| Actions taken: | Outcome: |

|  |  |
| --- | --- |
| Found by:……………………………….  Date:……………………………………. | Reported by:…………………………….  Date:……………………………………. |