**Protocol Violation and Deviation Form**

This form is to be used in the event of a protocol deviation or violation for imperial College AHSC sponsored clinical trials.

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| **Study Title** |  |
| **Sponsor Reference** |  |
| **Sponsor** |  |
| **EudraCT Number** |  |
| **CI/PI** |  |
| **Subject Number** |  |
|  |
| **Report Type**  | Violation [ ]   Deviation [ ]   | **Date of event** |  |
| **Description**  |  |
| **Investigator Informed?**  | Yes [ ]  No [ ]  | **Date** |  |
|  |  |  |  |
| **Action Required** | Subject to be withdrawn Yes [ ]  No [ ]  NA [ ]  |
| Subject to continue Yes [ ]  No [ ]  NA [ ]  |
| Breach of GCP or Protocol notice to Yes [ ]  No [ ]  NA [ ] be completed and sent toImperial RGIT |
| Other (specify) |
| **Sponsor informed?** | Yes [ ]  No [ ]  | **Date** |  |