**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| **Action Required** | Subject to be withdrawn Yes  No  NA | | | |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 to  Imperial RGIT | | | |
| Other (specify) | | | |
| **Sponsor informed?** | Yes  No | **Date** | |  |