# Protocol Violation and Deviation Form

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

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| **Action Required** | Participant to be withdrawn:Yes [ ]  No [ ]  NA [ ]  |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