# 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| **Action Required** | Participant to be withdrawn:  Yes  No  NA | | | |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** | |  |