**Protocol Deviation Log – Instructional**

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| **Purpose/Guidance:**The protocol deviation log can be used to track any deviation made from the IRB-approved protocol. This includes but is not limited to:* Researcher errors
* Enrollment errors/issues
* Missed study procedures
* Unauthorized personnel
* Missed study payments
* Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs)
* Adverse events
* Serious adverse events

Track deviations in real-time and ensure that any deviation which meets the IRB reporting requirements is met. |

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| **Customization:*** Include any relevant study information, including but not limited to:
	+ Sponsor name
	+ Study identifier (protocol number)
	+ Site #
 |

***The template starts on the next page.*Protocol Deviation Log**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Page \_\_\_\_\_\_ of \_\_\_\_\_\_**

**Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| Date | **Participant ID *(if applicable)*** | **Brief summary of event** | **Requires submission to the IRB** | **Reported to IRB *(check if yes)*** | **RNI Application # *(if applicable)*** | **Additional Comments** |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  |  |  | Y [ ]  N [ ]  | [ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |