**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: \_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
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