**FORM: Protocol Deviation Tracking Log**

**About:** This protocol deviation log is to provide a history of deviations for this protocol.

**Best Practice Recommendations:**

* Record protocol deviations in the tracking log as they occur, to ensure completeness and accuracy of the data.
* Number each page and maintain this log in the Essential Documents Binder, behind the Protocol Deviations tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File).
* Major deviations should be reported to the CHW IRB per the RNI Policy (Ref 15574)

**For studies with continuing reviews**: This protocol deviation log is to be submitted to the IRB with the yearly Continuing Review. Attach all correspondence concerning the following events that has occurred with the sponsor, if applicable. Only report deviations to the IRB that have occurred during the approval period. If the deviation was reported on a previous continuing review submission it need not be reported on a subsequent continuing review. The PI should sign each protocol deviation log prior to each continuing review submission. A new protocol deviation log should be started with each continuing review approval period.

**For studies without continuing reviews**: This protocol deviation log should be maintained and ready to present during routine reviews, including SAFE reviews. At the end of each calendar year, the PI should review and sign the protocol deviation log and a new protocol deviation log should be created for the next calendar year.

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| --- | --- |
| Protocol Name |  |
| IRB Number |  |
| Investigator |  |
| Primary Contact |  |

**Time Period:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date of Occurrence | Date Identified | Subject ID | Description of Deviation | Is this deviation reportable to the IRB?  Y/N | Rationale of why this deviation did not increase risk or cause harm | Steps taken to prevent future occurrence |
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*\*Add more table lines as required.*

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| --- | --- |
| Type of Deviations |  |
| **Major Deviations** | Deviations that may potentially have significant impact on the research plan, integrity of the data results and/or subjects’ rights, safety or welfare.  \*These deviations must be reported to the SH IRB within five (5) days of the PI becoming aware of such deviation or impact of such deviation via the RNI Form. |
| **Minor Deviations** | Deviations that do not significantly impact the research plan, integrity of the data results and/or subjects’ rights, safety or welfare.  \*These deviations can be reported to the SH IRB at the time of continuing review (if applicable) or study completion if continuing review was not required. |

**PI Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_**