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| Protocol Deviation Tracking Log | NJH HRPP Office |

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| --- | --- | --- |
| IRB Protocol #: | | DATE: |
| PROTOCOL TITLE: | | |
| PRINCIPAL INVESTIGATOR: | PHONE/(DIRECT) EXTENSION: | |
| IRB CONTACT: | PHONE/EXTENSION: | |

**Please refer to Decision Tree for Reportable Event Criteria**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Date Identified** | **Subject ID** | **Date of**  **Deviation** | **Event Description** | **Minor or Major**  **Deviation?** | **Date reported to**  **NJH HRPP Office,**  **Sponsor and**  **IRB of Record**  **if applicable** | **Did Subject**  **Continue in**  **Study?** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |
|  |  |  |  | **Minor**  **Major** |  | **Yes**  **No** |

Investigator’s Signature Date