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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