**NOTE:**

This form is intended to document waivers or deviations from a Standard Operating Procedure.

Report *protocol* deviations and exceptions in accordance with organization, department, or project requirements.

1. **REPORT DETAILS**

***[Please provide information regarding the SOP that is affected by the deviation or waiver]***

|  |  |  |
| --- | --- | --- |
| **Completed by** | **Date** | **Type**  □ Deviation □ Waiver |
| **SOP ID** | **SOP Version** | |
| **SOP Title** | | |

1. **ADDITIONAL INFORMATION (OPTIONAL)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Clinical Trial Name** |  | **HUM Number** |  |
| **Site Name(s)** |  | **Site Identifier(s)** |  |
| **Subject Identifier(s)** |  |  |  |
| **Other** |  | | |

1. **DESCRIPTION**

**Deviations:** *Provide a description of the circumstances which led to the deviation from standard practice and the steps that will be taken to correct the current situation and/or prevent additional occurrences.*

**Waivers:** *Provide a justification statement that supports the waiver request.*

***[If waivers and/or deviations are documented elsewhere, include a reference to the location of the documentation in the section below. Do not leave blank.]***



|  |
| --- |
| **SOP Administrator or Designee: (Waivers Only)** |
| □ Approved □ Denied |
| **Rationale:** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **APPROVAL** |  | |  |  |  |
| **Approver Name** (please print) | |  | **Approver Signature** |  | **Date** |