|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PAMQuIP | | **Adverse Event Log** | | |
|  | | |
| Principal Investigator |  | | Protocol # |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Study Title |  | Subject ID |  |

VCU IRB policy requires Principal Investigators (PIs) to report adverse events that pose unanticipated problems that involve risks to subjects or others. Upon discovery, if the PI deems the event an “Unanticipated Problem” a Prompt or Non-Prompt form must be completed and submitted to the IRB according to VCU IRB Policy.. PIs must follow reporting requirements of study sponsors and the FDA, where applicable, to report adverse events to those entities[[1]](#footnote-1). The following form is a template that may be used to document all adverse events. This form is not required by the VCU IRB.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Event** | **Date of Event** | **PI: Unanticipated Event?** | **PI Signature and Date** |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Event** | **Date of Event** | **PI: Unanticipated Event?** | **PI Signature and Date** |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |
|  |  | Unanticipated Event |  |

1. [↑](#footnote-ref-1)