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| PAMQuIP | **Unanticipated Problem WITH Potential Risk or Harm to Subjects or Others Log** |
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| Principal Investigator |  | Protocol # |  |

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| Protocol Title |  |

VCU IRB policy requires Principal Investigators (PIs) to report all protocol changes, deviations and exceptions to the Institutional Review Board (IRB). Upon discovery, if the PI deems the event an “Unanticipated Problem **with** potential or actual risk or harm to subjects or others” (affects subject safety, risks or benefits, data integrity and/or subject’s willingness to participate), the PI must complete the **Prompt Report** questions in RAMS IRB. This is to be completed and submitted to the IRB within 72 hours.

**This form should only be used for events that meet this definition:**

"Unanticipated Problem" (UP): An unanticipated problem involving risk to participants or others is defined by meeting ALL 3 of the following criteria:

1. Was not anticipated or foreseen;
2. Involves risk or harm to participants or others; AND
3. Was probably or definitely related to, or caused by, the research activity in the judgment of the investigator.

This template may be used to document Unanticipated Problems for study purposes, and/or to submit to the IRB with the next continuing review, if desired. This form is not required by the IRB

Otherwise, all Unanticipated Problems **without** actual or potential risk to subjects or others should be documented in RAMS IRB. If required by the sponsor or desired by the PI, the Unanticipated Problem WITHOUT…. can be filed with study record. .

**🡪 Unanticipated Problems WITH Potential risk or Harm to Subjects or Others**

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| **1.** | **Date of Unanticipated Problem:** |  |
|  | **Is this an Unanticipated Problem?** | No  Yes 🡪 complete a RAMS IRB Unanticipated Problem report and submit to IRB within 5 working days. |
|  | **Description of Event:**  *If available, please include:*   1. Explanation of why the event occurred, and 2. Description of any follow-up or corrective actions |  |
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|  | **PI Signature** |  |

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| **2.** | **Date of Unanticipated Problem:** |  |
|  | **Is this an Unanticipated Problem?** | No  Yes 🡪 complete a RAMS IRB Unanticipated Problem report and submit to IRB within 5 working days |
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|  | **PI Signature** |  |

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|  | **PI Signature** |  |

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|  | **PI Signature** |  |

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|  | **PI Signature** |  |