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| PAMQuIP | **Unanticipated Problem Log WITHOUT Risk/Harm to Subjects or others** |
| Study Organization Document |

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| Principal Investigator |  | Protocol # |  |

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| Protocol Title |  |

All Unanticipated Problems **without** actual or potential risk to subjects or others should be documented in RAMS IRB and submitted as part of the continuing review. If required by the sponsor or desired by the PI, this form can also be completed and kept with the study record. This form is a template that may be used to document Unanticipated Problems for study purposes, and/or to submit to the IRB with the next continuing review. Use of this form is not required by the IRB.

**This form should not 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.

If you have an Unanticipated Problem involving potential risk or harm to subjects or others, please report this in RAMS IRB. If desired, the PI can keep a log of such problems. Click on the link “Unanticipated Problem Log”.

**🡪 Unanticipated Problems WITHOUT potential risk or harm to subject 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 |
|  | **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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|  | **PI Signature** |  |