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| **IRB-HSR/ UVA Study Tracking#       PI:**  **Reviewer:       Meeting Date:** | | | |
| **Description of the Serious Adverse Event (SAE) or Unanticipated Problem (UP):**  *A copy of the Adverse Event Reporting Form and the AE Report from the database is attached.* | | | |
| ***Instructions: the board needs to determine the items below.*** | | | |
|  | **Yes** | **No** | **NA** |
| 1. Is any additional information needed from the investigators and/or others (pharmacy, legal, etc.) in order to evaluate this SAE/ UP? |  |  |  |
| 1. Are any additional actions required to protect subjects at this time?   *(Example: additional training, consent observation)*  *IF YES, describe:* |  |  |  |
| 1. Is the corrective action plan from the study team appropriate?  *If No describe additional actions required:* |  |  |  |
| 1. Are any modifications to the protocol or consent required due to this event? 2. *IF YES, describe:* |  |  |  |
| 1. If modifications to the consent are recommended, do all subjects actively participating in the study at this time need to be re-consented? |  |  |  |
| 1. Do subjects whose participation has ended need to be notified of the problem? |  |  |  |
| 1. Was this an internal event that meets the definition of an Unanticipated Problem? |  |  |  |
| 1. Must the study team report this event to the sponsor if they have not already done so? |  |  |  |
| 1. Are you requesting a PAM audit due to this event? |  |  |  |
| 1. Due to this event, is it necessary to suspend any part of the research?   *(Example: enrollment, treatment)* |  |  |  |
| 1. Due to this event, is it necessary to terminate/close the study? |  |  |  |
| 1. Is it necessary to increase the frequency of continuation reviews?   *If YES, how frequently should the study be reviewed?* |  |  |  |
| 1. Is any referral/notification required to any other UVA office (e.g. legal counsel, risk management, institutional official)?   *Must be YES if study suspended or terminated* |  |  |  |

**Additional Reviewer Comments:**

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IRB Member Name Date