|  |
| --- |
| **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:**

**\_\_**

IRB Member Name Date