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| NEW YORK STATE DEPARTMENT OF HEALTHInstitutional Review BoardHUMAN SUBJECTS ADVERSE EVENT REPORT |

**Please complete and sign this form electronically and submit to the IRB Administrative Office via IRBNet. Following review, IRB Administration will notify you of the IRB findings and any subsequent actions required.**

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| Principal Investigator:       IRB Reference #:      Title of Study     Date of Initial Approval:       Date of Most Recent Review:      \_Person Making the Report:      Date of Adverse Event:       Date First Known to You:      Name of Study Sponsor:      Date Reported to Study Sponsor:      Describe in detail the nature of the Adverse Event (AE) and timing of the event (attach additional documentation as needed):      |
| *The likelihood the Adverse Event was caused by the study is:*[ ]  **Probable** [ ] **Possible** [ ]  **Unlikely** [ ]  **Definitely unrelated** |
| ***Impact on Participant (check all that apply):***[ ]  Participant Died [ ]  Resulted in Disability[ ]  Required Follow-up Treatment [ ] Required First Aid[ ]  Resulted in Prolonged Hospitalization [ ]  Attention Beyond First Aid[ ] Participant Remains in Study [ ]  Other (Please Specify)        |
| ***Besides the DOH IRB, to whom has the Investigator reported this AE? (e.g., funding agency):***       |
| ***Describe corrective action taken by the Principal Investigator: (Check all that apply)***[ ]  Stop Enrollment of New Participants [ ]  Halt the Study[ ] Change Data Management/Coding Procedures [ ]  Form Committee to Review Procedures[ ] Police/Incident/Accident Report [ ]  Other (Please Comment):       |
| ***Does this event require revision to the (indicate Yes or No)?***[ ]  Protocol [ ]  Informed Consent Form [ ]  Both *If yes, please submit revised protocol and/or consent form to the IRB per the NYSDOH IRB Guidelines for Applicants*  |
| **Signature of Principal Investigator**      **Date:**       |
| If applicable, date special IRB session convened to consider AE:      Session Outcome:      Corrective Action Plan:      [ ]  Non- Compliance [ ]  Serious Non-Compliance [ ] Unanticipated Problem **Signature of IRB Chair:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |