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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:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |