

NewYork-Presbyterian/Queens  
Theresa & Eugene M. Lang Center for Research & Education  
**Unanticipated Problems Involving Risk to Subjects or Others Reporting Form**

<b>Sponsor:</b>	<b>IRB File#:</b>
<b>Title of Protocol:</b>	
<b>Principal Investigator:</b>	
<b>Name of Person Completing this Form:</b>	
<b>Email:</b>	<b>Phone</b>

**Study Status:**     Actively Enrolling       Enrollment Closed/Subject in F/U       Closed/No Subject Activity

**Describe the unanticipated event (include why it occurred and the outcome). Please append additional sheets or supporting documentation as necessary.**

**Did this event increase risk to the subject(s)?**                       No                       Yes - If **yes**, explain

**Did this event affect the integrity of the study data?**                       No                       Yes - If **yes**, explain

**Was this event caused by or probably caused by the test article, serious and unexpected?**                       No                       Yes - If **yes**, explain

**Does this event affect subjects enrolled in this study?**                       No                       Yes - If **yes**, explain

**Does this event affect anyone not enrolled in this study?**                       No                       Yes - If **yes**, explain

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Does this event involve an unanticipated device effect?

No

Yes - If **yes**, explain

**Corrective actions** must be listed below, including measures taken to ensure that similar problems do not occur in the future. *(If necessary, attach a separate page.)*

\_\_\_\_\_  
**Signature of Principal Investigator**

\_\_\_\_\_  
**Date**

**IRB Use Only**

Please consider whether the event

- Increase risks to subjects
- Changes the risk/benefit ratio for the research project
- Results in modifications required to the research project

Recommended IRB Action (Check all that apply)

- Acknowledge receipt and review
- Acknowledge receipt and review, AND request the following modification to the research:

- Warrants full board review. Please indicate reasons:

- Other action(s)

**IRB Reviewer's Printed Name:**

**Date**

**IRB Reviewer's Signature**