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Assessment:

You must make the following assessments:

1. This unanticipated problem resulted in an increased risk to subjects or others: Yes No

2. This unanticipated problem affected the rights, safety or welfare of the subject: Yes No

3. This unanticipated problem affected the integrity of the study: Yes No

4. Rationale for above selection: Describe the reason(s) you answered as you did above. What information supports your judgment?

5. Do you recommend any change to the protocol? Yes No
If yes, please attach recommended changes (marked in the protocol or a detailed summary).

6. Do you recommend any change to the consent document/template? Yes No
If yes, attach the consent changes, marking the changes in the document.

7. Has the sponsor reviewed these recommended changes? Yes No

Principal Investigator's Signature

Date: _____

Principal Investigator

Printed Name of Reporter