Serious Adverse Event (SAE) Reporting Form

Principal Investigator:	
Protocol Title:	
IRB #:	
Date of Report:	
Date of Event:	
Date PI/Study Team Notified:	

A. Patient Information

1. Participant Unique Identifier: _____
2. Date of Birth (MM/DD/YYYY): _____
3. Gender: ☐ Male ☐ Female
4. Weight: _____ ☐ lbs ☐ kg
5. Race:

   ☐ White or European American
   ☐ Asian American ☐ Black or African American
   ☐ American Indian or Alaska Native
   ☐ Native Hawaiian or other Pacific Islander
   ☐ Mixed Origin, specify:
   _____

6. Ethnicity**:** ☐ American Hispanic or Latino ☐ Not American Hispanic or Latino

B. Adverse Event/Product Problem

1. Medical Indication/Diagnosis: _____

   ICD-10 Code(s): _____

2. Outcome Attributed to Adverse Events:

   ☐ Death, Date of Death _____
   ☐ Life-threatening
   ☐ Hospitalization
   ☐ Other Serious or Important Medical Events
   ☐ Required Intervention to Prevent Permanent Impairment/Damage
   ☐ Disability or Permanent Damage
   ☐ Congenital Anomaly/Birth Defects

3. Adverse Event Type

   ☐ Adverse Event
   ☐ Product Use/Medication Error
   ☐ Product Problem
   ☐ Problem with Different Manufacturer of Same Medicine

4. Describe Event (including CTCAE v5.0 grade, as applicable):

Relevant Tests/Laboratory Results (including dates):

☐ None/Not Applicable

Related Therapies (including dates and dosages):

☐ None/Not Applicable

Relevant Concomitant Medications:
(Include: Indication, Start Date, End Date, Dose, Frequency, and Route)

☐ None/Not Applicable

Other relevant medical history:

☐ None/Not Applicable

5. Causality of Adverse Event:

☐ Unrelated to Investigational Product
☐ Unlikely related to Investigational Product
☐ Likely related to Investigational Product
☐ Related to Investigational Product

Reported to IRB ☐ Yes, Date: ☐ No/NA, Describe Reason Not Reportable:

Reported to Sponsor ☐ Yes, Date: ☐ No/NA, Describe Reason Not Reportable:

Reported to FDA ☐ Yes, Date: ☐ No/NA, Describe Reason Not Reportable:

C. Reporter Information

First Name:	
Last Name:	
Study Role:	
Contact Phone Number:	
Contact Email Address:	
Address:	
Health Professional:	☐ Yes, Credentials: ☐ No

PI/MD Signature: _____ Date: _____

PI/MD Printed Name: _____