

# Severe Adverse Event\*

**Form #:**       
 **Visit #:**       
 **Subject #:**   -         
 **Initials:**         
 **Date:** (mm-dd-yyyy)   -   -

\*Report to your institution's IRB

## 1. Patient Details

**Date of Birth:** (mm-yyyy)   -         
 **Sex:**  (M=Male; F=Female)

**Height**    .  cm     
 **Ethnicity:** Hispanic/Latino?  (Y=Yes, N= No)

**Weight**    .  kg

**Race:**       
 AM = American Indian/Alaskan Native      MR = More than one race  
 AS = Asian      UN = Unknown or not reported  
 NH = Native Hawaiian/Other Pacific Islander  
 BL = Black/African American  
 WH = White

## 2. Principal Investigator Details

**Name:** \_\_\_\_\_      **Phone:**    -    -

**Address:** \_\_\_\_\_  
 \_\_\_\_\_

## 3. State Main Adverse Event

\_\_\_\_\_      **Onset date:**   -   -      
 (mmddyyyy)

**Resolved?**  (Y=Yes; N=No)     
 **If yes, resolution date:**   -   -      
 (mmddyyyy)

**Does the patient have prior history of this type of event?**  (Y=Yes; N=No)

**If yes, please describe:** \_\_\_\_\_

## 4. Describe Event(s) Give a chronological summary of signs and symptoms. Please provide diagnosis, treatment, outcome, and autopsy results, if appropriate.

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