

**GENESYS HEALTH SYSTEM-SERIOUS ADVERSE EVENT FORM**  
**For SAE's Occuring Within GHS –(Internal)**

**Study Title:**

**Today's Date:**

**GRMC Number:**

**Patient Number:**

**Event:**

**Event Date:**

A life threatening condition

Hospitalization (initial or prolonged)

A significant disability/incapacity or  
required intervention to prevent permanent damage

Death

**Description of Event:**

**What was the outcome of this event? Check all that apply.**

Discontinued from study

Study drug withdrawn temporarily

Death

Outcome not yet determined

Resolved/Recovered

Other

**What was the cause of the SAE?** - Check one box in each section and explain *why* in box below

**Subjects underlying disease, process, or condition:**

Unrelated     Unlikely     Likely     Definite     N/A

**Study's procedure:**

Unrelated     Unlikely     Likely     Definite     N/A

**Study's Drug/Device:**

Unrelated     Unlikely     Likely     Definite     N/A

**Give rationale for rating above:**

**PI Recommendation:**

Before the Institutional Review Board (IRB) conducts its review of the serious adverse events, the IRB requires you as principle and/or co-investigators to give us recommendations as indicated below.

**Choose one:**

- The SAE(s) is included in the possible complication/risk section of the informed consent
- One or more SAE, as I have stated, is not stated in the possible complication/risk section of the informed consent; however, I do not feel it is necessary to amend the consent form at this time
- I recommend modification of the informed consent to include new possible complications/risks as identified by this/these SAE(s).

**Mark all that apply:**

- I recommend continuation of the project
- I recommend modification of the informed consent to include new possible complications/risks as identified by this SAE
- I recommend discontinuation of the project until the SAE(s) can be investigated

**Signature** \_\_\_\_\_

Signature of Principle Investigator/Co-investigator

Date \_\_\_\_\_

**Print Name** \_\_\_\_\_

Genesys Health System - Institutional Review Board  
Office of Research, 2442  
Genesys Regional Medical Center  
One Genesys Parkway

Submit SAE Report – via [www.IRBnet.org](http://www.IRBnet.org)  
Electronic signature is accepted.

Grand Blanc, MI 48439