Date Received: _____

Memorial Health University Medical Center
Institutional Review Board

SUBMISSION OF SERIOUS ADVERSE EVENT REPORT FOR ORIGINAL STUDY

Study Title:

MHUMC Study Number *(assigned by IRB):*

Principal Investigator Information:
Name: Phone:
Address: Email:

Program Director: **Study Coordinator:**

DETAILS OF EVENT

☐ Initial ☐ Follow-up ☐ Final (If follow-up or final, provide initial SAE #:)

Date of Event: Date of Initial Awareness by Research Team:

Type of Event:
☐ Hospitalized ☐ Life-threatening ☐ Other Serious ☐Persistent Disability ☐ Congenital Anomaly ☐ Death

Event Relationship to Study Drug:
☐ Related ☐ Probably Related ☐ Possibly Related ☐ Not Related ☐ Probably Not Related ☐Undetermined

Subject Information:
Age: Gender: ☐ Male ☐ Female ID:

Status in Study: ☐ Continued ☐Discontinued ☐ Tx on hold/Interrupted ☐ Died ☐ Unknown

Brief Description of Event:

Is this type of event expected for this particular study? ☐ Yes ☐ No

As a result of this SAE, does the Informed Consent need to be revised to include new risk?
☐ No ☐ Yes (attach copy)

_____ _____
Principal Investigator Date Program Director Date

**** * * Section below for IRB administrative use only * * ****

☐ Accepted as information. SAE #: _____

_____ _____ IRB Agenda: _____
IRB Chair Date