**SERIOUS ADVERSE EVENT**

Return this form to: Baptist IRB [Baptist.IRB@bmhcc.org](file:///%5C%5CMTCCBMHFP%5CPUBLIC%24%5CClinical%5CBCRI%5CIRB%5CIRB%5CIRB%20Administrative%20Operations%5CCurrent%20Forms%5CLatest%20IRB%20Forms%202018%5CIRB%20Applications%5CRevised%20Applications%206-1-18%5CBaptist.IRB%40bmhcc.org) (Baptist IRB)

Patient Initials: \_\_\_\_\_\_\_\_\_\_ Patient Study ID#: \_\_\_\_\_\_\_\_\_\_

IRB Number: \_\_\_\_\_\_\_\_\_\_\_\_ Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Site#: \_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Report: \_\_\_\_\_\_\_\_\_\_ Patient Age: \_\_\_\_\_\_\_\_\_\_ Gender: \_\_\_\_\_\_\_\_

Name of SAE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SAE onset date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_ (if applicable)

Severity: [ ]  Mild [ ]  Moderate [ ]  Severe

Relation to Study: [ ] Not Related [ ] Doubtful [ ] Possible [ ] Probable

Resolution: [ ] Recovered [ ] Recovered with sequelae [ ] Recovered without sequelae

 [ ] Ongoing [ ] Death [ ] Unknown

Describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Unanticipated Problems Involving Risks to Subjects or Others? [ ] No [ ] Yes

PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_