**SERIOUS ADVERSE EVENT**

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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: \_\_\_\_\_\_\_\_\_\_