Sponsor Notification of Adverse Event

1. Study Information

Protocol Title

Protocol Number

Sponsor Name

Study Site

Principal Investigator (PI)

Study Coordinator

2. Subject Information

Subject ID

Date of Birth / Age

Sex

Enrollment Date

3. Adverse Event Details

Adverse Event Term / Diagnosis

Description of Event

Severity (Mild/Mod/Sev)

Onset Date

End Date

Serious? (Y/N)

Outcome

Treatment Required

Is Event Related to Study Drug/Device?

Action Taken with Study Drug/Device

4. Reporting Information

Date Site Became Aware

Notified to Sponsor On (Date)

Notified by (Name & Title)

5. Additional Comments

Signature (PI)	Date