Standardized Adverse Events Reporting Form: Spontaneous Reporting

Study Participant ID: _____

Date this column completed: _____/_____/_____

Initials of person completing this column: _____

Source: *(Check all that apply)*
☐ Participant's Physician: _____
☐ Telephone Check-in
☐ Phone call from participant
☐ Other, Specify:_____

AE date: _____/_____/_____

Describe nature and sequence of events:

Action taken: *(Check all that apply)*
☐ None
☐ Self-treatment
☐ Physician visit
☐ Out-patient procedure
☐ Hospitalization
☐Other, describe:_____

_____

_____

Has the adverse event resolved? *(Check one only)*
☐ Yes – no action needed
☐ No – provide plan under "Action to be taken"

Check all that apply:
☐ Allergy/Immunologic
☐ Cardiovascular
☐ Skin
☐ Endocrine
☐ Ear, Nose, Throat
☐ Eyes
☐ Gastrointestinal
☐ Genitourinary
☐ Hematological
☐ Musculoskeletal
☐ Neurological
☐ Psychiatric
☐ Respiratory
☐ Other: _____

FDA Serious (SAE)? ☐ No ☐ Yes *(Check one only)*

If FDA Serious, Type of SAE: *(Check one only)*
☐ Death *(Grade 5)* Date: _____/_____/_____
☐ Life threatening *(Grade 4)*
☐ Inpatient hospitalization or prolongation of existing hosp. *(Grade 3)*
☐ Event requiring intervention to prevent above
☐ Other, Describe: _____

If NOT Serious, Grade: (*Check one only)*
☐ Mild/Grade 1 *(No intervention; asymptomatic lab or radiographic findings; marginal clinical significance)*
☐ Moderate/Grade 2 *(OTC or single-physician visit; AE limited activities of daily living (ADLS) for <48hrs.)*
☐ Severe/Grade 3 *(AE significantly limited basic self-care but did not require initial hospitalization or prolongation of hospitalization (see above); Not immediately life-threatening but disabling)*

☐ Check box if NOT considered an adverse event, explain:

_____

Action to be taken: *(Check one only)*
☐ Notify PI immediately *(AE graded 4 or 5)*
☐ Notify PI
☐ Add to participant's study chart
☐ Add to AE reporting file
☐ Other monitoring: _____

_____

Study follow-up, participant will: *(Check one only)*
☐ Continue in study
☐ Withdraw from treatment, continue follow-up interviews
☐ Withdraw from treatment and follow-up interviews
☐ Withdraw from follow-up interviews *(treatment complete or N/A)*

Final Resolution, if monitoring plan given: _____

_____

Date of Final Resolution: _____/_____/_____ **Study PI sign-off Date:** _____/_____/_____