

ID \_\_\_\_\_ - **ID** \_\_\_\_\_ - \_\_\_\_\_

**ADVERSE EVENT FORM**

Date of onset (mm/dd/yy)	Study Activity (code)  10 = 400 meter 20 = Stepwatch 30 = Environment 40 = Phlebotomy 50 = Phy. Measure 60 = Other	Event (code)  See codes on back	Relationship to study  0=not related 1=possible related 2=probably related 3=definitely related 4=indeterminate	Serious adverse event? N = No Y = Yes  <i>(See definition of SAE on back of form)</i>	Severity  1=mild 2=moderate 3=severe 4=life threatening 5=death	Action taken  1=none 2=out-patient evaluation 3=hospitalization 4=other	Outcome date (mm/dd/yy)	Outcome Status  1=resolved 2=continuing 3=controlled 4=death	For office use only	
									Entered	Verified
<b>ONM/OMD/OMY</b> ___/___/___	<b>LABSACT</b> (If other, specify: <b>LABSACTS</b> )	<b>AE_CODE</b> (If other, specify: <b>AE_CODES</b> )	<b>RELATION</b>	<b>SAE</b> N Y	<b>AE_SEVER</b>	<b>AE_ACT</b> (If other specify: <b>AE_ACTS</b> )	<b>OUTM/OUTD/OUTY</b> ___/___/___	<b>OUTSTAT</b>	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y
___/___/___	(If other, specify: _____)	(If other, specify: _____)	___	N Y	___	(If other specify: _____)	___/___/___	___	Y	Y

Event codes:

400 Meter Corridor Walk

- 01 = angina, chest pain, tightness, or pressure
- 02 = trouble breathing, shortness of breath, wheezing or dyspnea
- 03 = MI
- 04 = stroke
- 05 = lightheaded or dizzy
- 06 = loss of consciousness
- 07 = back pain
- 08 = hip pain
- 09 = knee pain
- 10 = calf pain, leg cramps
- 11 = foot pain
- 12 = numbness or tingling in legs or feet
- 99 = other-specify

Environmental Related

- 01 = skin or peripheral nerve pressure injury (from too small chair, etc)
- 02 = physical injury occurring during research visit (e.g. fall walking during visit)
- 03 = physical injury occurring to/from visit (e.g. fall getting out of car)
- 04 = staff injury (e.g. coordinator injured while transporting study equipment)
- 99 = other-specify

Stepwatch Monitor

- 01 = skin and peripheral nerve pressure injury (from band/monitor)
- 02 = back pain (from bending over to put on/remove monitor)
- 99 = other-specify

Phlebotomy related

- 01 = temporary discomfort or bruising
- 02 = infection at the skin puncture site
- 03 = fainting
- 99 = other-specify

Physical Measurement Related

- 01 = Numbness and/or tingling during use of equipment (e.g. while BP Cuff is inflated) but goes away immediately after equipment is removed
- 02 = Numbness and/or tingling that persists after equipment is removed
- 03 = Skin bruising
- 99 = Other

Other

- 01 = breach of confidentiality

**NOTE:** This list is not all inclusive and the recording of an adverse event remains at the discretion of the investigator. A symptom or condition that is present but does not fit one of these levels may still be recorded as an adverse event.

Definition of Serious Adverse Event

A serious adverse event is defined as fatal or life-threatening, requires or prolongs hospitalization, produces a significant or permanent disability, or results in a congenital anomaly/birth defect.

Severity Definitions:

- Mild: awareness of sign or symptom, but easily tolerated.
- Moderate: discomfort sufficient to cause interference with normal activities.
- Severe: incapacitating, with inability to perform normal activities.
- Life threatening: imminent peril of loss of life.
- Death: Death has occurred.

Relatedness to the study:

- Not related: Indisputably not related to any of the categories.
- Possibly related: Unlikely but uncertain as to whether the event is related to the category.
- Probably related: Likely but uncertain as to whether the event is related to the category.
- Definitely related: Indisputably related to any of the categories.
- Indeterminate: complete lack in clarity or judgment as to whether the event is related to the category.

Outcome status:

- resolved: Patient returned to previous health status with no subsequent problems.
- continuing: Patient has not yet returned to previous health status and continues to be followed for the AE.
- controlled: Event is present but is controlled.
- death: Death has occurred.