

ID \_\_\_\_\_

## ADVERSE EVENT FORM

Date of onset (mm/dd/yy)	Study Activity (code)	Event (code)	Relationship to study  0=not related 1=possible related 2=probably related 3=definitely related 4=indeterminate	Serious adverse event?  N = No Y = Yes  (See definition of SAE on back of form)	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
_____/____/____	10 = 400 meter 20 = Stepwatch 30 = Environment 40 = Phlebotomy 50 = Phy. Measure 60 = Other	See codes on back								
_____/____/____	<b>LABSACT</b> (If other, specify: <u>LABSACTS</u> )	<b>AE_CODE</b> (If other, specify: <u>AE_CODES</u> )	<b>RELATION</b>	N Y	<b>AE_SEVER</b>	<b>AE_ACT</b> (If other specify: <u>AE_ACTS</u> )	OUTM/OUTD/OUTY _____/____/____	OUTSTAT	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	
_____/____/____	(If other, specify: _____)	(If other, specify: _____)	____	N Y	____	(If other specify: _____)	_____/____/____	____	Y Y	

Event codes:

<b>400 Meter Corridor Walk</b>	<b>Environmental Related</b>
01 = angina, chest pain, tightness, or pressure	01 = skin or peripheral nerve pressure injury (from too small chair, etc)
02 = trouble breathing, shortness of breath, wheezing or dyspnea	02 = physical injury occurring during research visit (e.g. fall walking during visit)
03 = MI	03 = physical injury occurring to/from visit (e.g. fall getting out of car)
04 = stroke	04 = staff injury (e.g. coordinator injured while transporting study equipment)
05 = lightheaded or dizzy	99 = other-specify
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	
<b>Stepwatch Monitor</b>	<b>Phlebotomy related</b>
01 = skin and peripheral nerve pressure injury (from band/monitor)	01 = temporary discomfort or bruising
02 = back pain (from bending over to put on/remove monitor)	02 = infection at the skin puncture site
99 = other-specify	03 = fainting
	99 = other-specify
<b>Physical Measurement Related</b>	<b>Other</b>
01 = Numbness and/or tingling during use of equipment (e.g. while BP Cuff is inflated) but goes away immediately after equipment is removed	01 = breach of confidentiality
02 = Numbness and/or tingling that persists after equipment is removed	
03 = Skin bruising	
99 = Other	
<b>NOTE:</b> 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.   |