

ID _____ - _____ - _____ ID

LABS-3 PSYCHOSOCIAL ADVERSE EVENT FORM

Date of onset (mm/dd/yy) PONM / POND / PONY	Study Activity (code) 10 = Psychological 20 = Environment 30 = 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) POUTM / POUTD / POUTY	Outcome Status 1=resolved 2=continuing 3=controlled 4=death	For office use only	
									Entered	Verified
___/___/___	PIBSACT <i>(If other, specify: PIBSACTS)</i>	PAE_CODE <i>(If other, specify: PAE_CODS)</i>	PRELATE ___	PSAE N Y	PAE_SEVR ___	PAE_ACT <i>(If other specify: PAE_ACTS)</i>	___/___/___	POUTSTAT ___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y
___/___/___	<i>(If other, specify: _____)</i>	<i>(If other, specify: _____)</i>	___	N Y	___	<i>(If other specify: _____)</i>	___/___/___	___	Y	Y

Event codes:

<p><u>Psychological Related</u></p> <p>01 = Emotional distress due to interview(s) 02 = Emotional distress due to questionnaires 03 = Emotional distress due to NDS 99 = Other - specify</p> <p><u>Environmental Related</u></p> <p>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</p> <p>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.</p>	<p><u>Other</u></p> <p>01 = breach of confidentiality</p>
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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.