

Section 1: V5/NCS Administrative Forms**Serious Adverse Event Form: FORM CODE=SAE VERSION=1.0**

Instructions: This form should be completed within 24 hours of a serious adverse event. Serious adverse events (SAEs) are unanticipated and unexpected, whether study-related or otherwise.

<i>Vers</i>		<i>Vers</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	0100	

<i>EventName</i>		<i>EventName</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Administrative Forms	

<i>Occurrence</i>		<i>Occurrence</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	1	

<i>SAE0a</i>		<i>Completion Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Range	11/22/2011 - 05/16/2012

<i>SAE0b</i>		<i>Staff ID</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Present	Text suppressed

<i>SAE1</i>		<i>Contract number</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	Present	Text suppressed
4		Missing

<i>SAE2</i>		<i>Principal Investigator</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Present	Text suppressed

<i>SAE3</i>		<i>Field Center</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
4	J	Jackson
1	M	Minneapolis

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SAE4		<i>More than one event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	N	No

SAE5		<i>Event Number</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	.S	Legitimately skipped

SAE6		<i>Occurrence Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Range	11/22/2011 - 05/14/2012

SAE7a		<i>Principal Investigator Reported</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Y	Yes

SAE7a1		<i>Principal Investigator Report Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Range	11/22/2011 - 05/14/2012

SAE7b		<i>Field Center Reported</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	N	No
4	Y	Yes

SAE7b1		<i>Field Center Report Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
4	Range	11/22/2011 - 05/16/2012
1	.S	Legitimately skipped

SAE8		<i>Category of SAE</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
4	C	Requires hospitalization
1	D	Associated with disability/incapacity

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<i>SAE9</i>		<i>Event Description</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Present	Text suppressed

<i>SAE10</i>		<i>Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
2	1	Ongoing
3	2	Resolved

<i>SAE11</i>		<i>Action Description</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	Present	Text suppressed

<i>SAE12</i>		<i>Related to ARIC</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
2	A	Unrelated (clearly not related)
2	B	Unlikely (doubtful related)
1	C	Possible (may be related)