

Section 2: V6 / NCS Adverse Events Forms**Minor Adverse Event Form: FORM CODE=MAE VERSION=0100**

Instructions: This form should be completed within 7 days of a minor adverse event. Minor adverse events (MAEs) are anticipated and expected to occur as stated risks in the study protocol, whether study related or otherwise.

<i>Vers</i>		<i>Vers</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	0100	

<i>EventName</i>		<i>EventName</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	V6 / NCS Adverse Events	

<i>Occurrence</i>		<i>Occurrence</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	1	

<i>MAE0a</i>		<i>Completion Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Range	07/19/2016 - 01/11/2018

<i>MAE0b</i>		<i>Staff ID</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed

<i>MAE1</i>		<i>Contract No</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed

<i>MAE4</i>		<i>Multiple events during visit</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
26	N	No
1	Y	Yes

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<i>MAE5</i>		<i>Count for this event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	Range	1 - 1 (median=1 mean=1.0 std=)
26	.S	Legitimately skipped

<i>MAE6</i>		<i>Date MAE occurred</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Range	06/29/2016 - 01/11/2018

<i>MAE7a</i>		<i>MAE reported to Principal Investigator</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Y	Yes

<i>MAE7a1</i>		<i>Date MAE reported to Principal Investigator</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Range	06/29/2016 - 01/11/2018

<i>MAE7b</i>		<i>MAE reported to Field Center IRB</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
26	N	No
1		Missing

<i>MAE7b1</i>		<i>Date MAE reported to Field Center IRB</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	.S	Legitimately skipped

<i>MAE8</i>		<i>MAE source</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
2	B	Blood draw
16	D	Other physical examination tests
9	E	Other

<i>MAE10</i>		<i>Status of event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
9	O	Ongoing
18	R	Resolved

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<i>MAE12</i>		<i>Is type of event foreseen</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
11	N	No
16	Y	Yes

<i>MAE13</i>		<i>Likelihood that event related to ARIC</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
3	A	Unrelated (clearly not related)
6	B	Unlikely (doubtful related)
1	C	Possible (may be related)
1	D	Probable (likely related)
16	~	Legitimately skipped

<i>MAE2_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed

<i>MAE3_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed

<i>MAE9_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed

<i>MAE11_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
27	Present	Text suppressed