

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

**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>
80	0100	

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

<i>Occurrence</i>		<i>Occurrence</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
79	1	
1	2	

<i>MAE0a</i>		<i>Completion Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	Range	06/24/2011 - 07/30/2013

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

<i>MAE1</i>		<i>Contract number</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
35	Present	Text suppressed
45		Missing

<i>MAE2</i>		<i>Principal Investigator</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	Present	Text suppressed

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<i>MAE3</i>		<i>Field Center</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
5	F	Forsyth
47	J	Jackson
26	M	Minneapolis
2	W	Washington

<i>MAE4</i>		<i>More than one event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	N	No

<i>MAE5</i>		<i>Event Number</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	~	Legitimately skipped

<i>MAE6</i>		<i>Occurrence Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	Range	06/24/2011 - 07/29/2013

<i>MAE7a</i>		<i>Reported to Principal Investigator</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
3	N	No
77	Y	Yes

<i>MAE7a1</i>		<i>Principal Investigator Reported Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
77	Range	06/24/2011 - 07/30/2013
3	.S	Legitimately skipped

<i>MAE7b</i>		<i>Reported to Field Center IRB</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
25	N	No
55	Y	Yes

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<i>MAE7b1</i>		<i>Field Center Reported Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
55	Range	04/24/2012 - 12/19/2012
25	.S	Legitimately skipped

<i>MAE8</i>		<i>Event Source</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
2	A	Interview with study participant
4	B	Blood draw
2	C	Lung function testing
58	D	Other physical examination tests
14	E	Other, report in note log

<i>MAE9</i>		<i>Event Description</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	Present	Text suppressed

<i>MAE10</i>		<i>Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	R	Resolved

<i>MAE11</i>		<i>Action Description</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
80	Present	Text suppressed

<i>MAE12</i>		<i>Event forseen</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
69	N	No
11	Y	Yes

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<i>MAE13</i>		<i>Relationship to participation in ARIC</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
6	A	Unrelated (clearly not related)
2	B	Unlikely (doubtful related)
2	C	Possible (may be related)
1	D	Probably (likely related)
58	E	Definite (clearly related)
11	~	Legitimately skipped