

Section 2: V6 / NCS Adverse Events Forms**Unanticipated Problem Form: FORM CODE=UPR VERSION=0100**

Instructions: This form should be completed within 48 hours of an Unanticipated Problem (UP). UPs include any experience or outcome that is unexpected, and related or possibly related to participation in ARIC, and suggestive that the research places subjects or others at a greater physical, psychological, economic, or social risk or harm than was previously known.

<i>Vers</i>		<i>Vers</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	0100	

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

<i>Occurrence</i>		<i>Occurrence</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	1	

<i>UPR0a</i>		<i>Completion date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Range	08/22/2016 - 01/12/2018

<i>UPR0b</i>		<i>Staff ID</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed

<i>UPR1</i>		<i>Contract number</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed

<i>UPR4</i>		<i>Date UP occurred</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Range	08/19/2016 - 12/22/2017

<i>UPR5a</i>		<i>UP reported to PI</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
2	0	0=No
6	1	1=Yes

Section 2: V6 / NCS Adverse Events Forms

<i>UPR5b</i>		<i>Date UP reported to PI</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
6	Range	08/19/2016 - 01/12/2018
2	.S	Legitimately skipped

<i>UPR5c</i>		<i>UP reported to Field Center IRB</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
7	0	0=No
1	1	1=Yes

<i>UPR5d</i>		<i>Date UP reported to IRB</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	Range	08/24/2016 - 08/24/2016
7	.S	Legitimately skipped

<i>UPR6</i>		<i>Source of unanticipated problem</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
4	3	3=Other physical examination or tests
4	4	4=Other (specify)

<i>UPR6a</i>		<i>Other UP event source</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
4	Present	Text suppressed
4	~	Legitimately skipped

<i>UPR8</i>		<i>Resolution status of UP event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	1	1=Ongoing
7	2	2=Resolved

<i>UPR2_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed

Section 2: V6 / NCS Adverse Events Forms

<i>UPR3_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed

<i>UPR7_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed

<i>UPR9_status</i>		<i>Label information missing in the dataset</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
8	Present	Text suppressed