

7. Describe the event (limit to 250 words or less)

8. Indicate whether the event is: Ongoing _O Resolved _R

9. Describe what action was taken (limit to 250 words or less)



Unanticipated Problem Reporting Form

UPR- QxQ Instructions

Introduction

The UPR form is completed within 48 hours of any experience or event that is unexpected, and related (or possibly related) to participation in ARIC, that may suggest that the research places the study participant or others at greater risk of physical, psychological, economic, or social harm than was previously known.

See ARIC Visit 6 Manual 2, Section 19 for a definition of unanticipated problems (UPs) and their classification. That information is critical to an appropriate classification of an event or occurrence as a UP and must be considered before selecting this form to record and document the UP.

Once the study participant's safety and comfort have been addressed following a UP, a UPR form is entered into CDART. The ARIC field center staff entering the UPR form in CDART then notifies the ARIC coordinating center by sending an email with the study participant ID to arichelp@unc.edu. These actions result in a review of the event by coordinating center personnel and a report of the UP to the NHLBI by the Coordinating Center, within 72 hours. No direct notification of a UP to NHLBI is required from the field center unless additional information is requested. Field centers also follow their Institution's protocol that may require notification of the study PI and the IRB.

This form may be accessed more than once, since information may not be complete at the time of initial entry about actions taken by the field center concerning the adverse event. Similarly, updates may be needed once more information related to the SAE becomes available. Arichelp@unc.edu should be notified if a UPR form is updated or the event is re-classified.

A. Event information.

Before filling the UPR form obtain as much information about the event as possible. Information summarizing the event and its circumstances, such as triggering factors, signs and symptoms experienced by the study participant, the duration of the condition, and the apparent causes are informative in documenting the event and assist reviewers.

The information on the ARIC field center contract at this institution, the name of the ARIC principal investigator and field center are recorded in items 1-3. The date the UP occurred, and whether it was reported to the principal investigator and to the field center IRB, as well as the respective dates of these reports is recorded in items 4 and 5.

Item 6 indicates whether the UP was associated with a main component of the ARIC examination, or whether it is associated with other elements of an individual's participation in this study. If so, specify under Item 6.

A text field is provided under Item 7 to describe the event, succinctly but in sufficient detail to determine its nature and potential severity. The circumstances surrounding the UP or leading to

its occurrence should be mentioned. Enter as much detail about the UP as possible to assist reviewers get an accurate picture of what occurred and of the setting.

Item 8 indicates whether at the time of reporting the UP is ongoing or resolved.

Item 9 presents a text field to summarize the action taken in response to the UP. Describe what action(s) were taken by the field center staff, the medical director and/or the Principal Investigator. Indicate whether medically trained personnel was present or contacted, the timing of various actions taken in response to the UP, the study participant's response, and the resolution of the UP.

The UPR form may be filled in consultation with a supervisor or medically trained personnel. It may also be updated after review by the medical director or the ARIC principal investigator.