INSTRUCTIONS FOR UNANTICIPATED PROBLEM REPORTING FORM (UPR)

Introduction

An unanticipated problem (UP) in ACHIEVE is defined as an incident, experience, or outcome that meets all of the following criteria:

- Unexpected – in terms of nature, severity, or frequency given the procedures and interventions used in the ACHIEVE study as described in the protocol and informed consent given the characteristics of the study population
- Possibly or definitely related to the participation in the ACHIEVE study
- Suggests that the research places the participant or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

Some adverse events may also qualify as unanticipated problems, and an adverse events form should also be filled out as needed. The UPR form is completed within 48 hours of any unanticipated problem.

Once the study participant's safety and comfort have been addressed following a UP, the field site medical director and field site PI should be notified. Within 48 hours, a UPR form is entered into CDART. The field center staff entering the UPR form in CDART then notifies the ARIC coordinating center. Within 48 hours, the UP should be reported by the field site PI to the site IRB and by the ACHIEVE PI to the DSMB and NIA.

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. The coordinating center 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.

Item 1 asks about the Contract number. Leave this field BLANK. The UPR form is shared across both ARIC and ACHIEVE, and this field is only relevant for ARIC.

Items 2-3 requests the ACHIEVE field site principal investigator and field center

Items 4-5 inquire about 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.

Item 6 asks which component of the ACHIEVE study the UP was associated with.

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 ACHIEVE principal investigator.