



HCHS/SOL Unanticipated Problem Reporting Form

UPR- QxQ Instructions

Introduction

The UPR form is completed within 48 hours of an event or occurrence that qualifies as an unanticipated problem (UP) ostensibly related to participation in the HCHS/SOL. A UP is defined as any experience or outcome that is unexpected, and related (or possibly related) to participation in SOL, and is suggestive that the research places the study participant or others at greater risk of physical, psychological, economic, or social harm than was previously known. UPs are reported to the local IRB, to the study PI, and to NHLBI (via the SOL coordinating center). Completing the UPR form will accomplish this latter notification requirement.

A. Event information.

This section is pre-formatted to record the information on the SOL field center contract, the principal investigator and field center, 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 indicates whether the UP was associated with a main component of the visit 2 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.

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

Finally, Item 9 presents a text field to briefly summarize the action taken in response to the UP.

B. Actions Taken.

Section B is to be completed at the SOL coordinating center.