



SOL INCA MRI Unanticipated Problems

UPM– QxQ

5/30/2018

Introduction

The UPM form is completed within 48 hours of an event or occurrence that qualifies as an unanticipated problem (UP) ostensibly related to participation in the SOL-INCA-MRI. A UP is defined as any experience or outcome that is unexpected, and related (or possibly related) to participation in SOL-INCA-MRI, 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-INCA-MRI coordinating center). Completing the UPR form will accomplish this latter notification requirement.

A. Event information.

- Item 1-5;** this section is pre-formatted to record the information on the HCHS/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 MRI visit examination, or whether it is associated with other elements of an individual's participation in this study. If so, specify under Item 6.
- Item 7;** provides a text field 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.
- 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-INCA-MRI coordinating center.