HCHS/SOL- Unanticipated Problem (UPR)

QXQ

2/5/2020

General Instructions

Unanticipated Problems (UPs) include any experience or outcome that is unexpected, and related or possibly related to participation in HCHS/SOL, and suggestive that the research places subjects or others at a greater physical, psychological, economic, or social risk or harm than was previously known.

An adverse event (AE) is an adverse change in health or unfavorable medical occurrence that occurs in a person who participates in HCHS/SOL, which may or may not be caused by participation in the study. Unanticipated problems may include both physical and psychological harms. Refer to Manual of Operations #2 on the Field Center Examination Procedures for Visit 3 for definitions and details on Unanticipated Problems.

Timeline for form completion. This form should be completed in CDART within 48 hours of the event.

Reporting. UPs are reported to the CC – and through it to the sIRB, – to the NHLBI and the HCHS/SOL steering committee. This is accomplished by completing the form in CDART, and by notifying the CC that a UPR has been submitted via an email to HchsAdverseEvent@unc.edu.

Notification of the local IRB. Completing the UPR form in CDART allows the CC to notify the sIRB (at UNC) and creates the required log of UPs. Notification of the field center's local IRB is to be specified by the site IRB. If the local IRB requires notification of a UP, item 5 serves to record the date by which the local IRB was notified.

Timelines for notifications and review. A copy of Table 15 from MOP 2 - Visit 3 Core Study is provided below as an overview of actions and timing.

Table 15. Types of unanticipated problems and adverse events, and required actions by the HCHS/SOL Staff and Timing

HCHS/SOL- Unanticipated Problem (UPR)

QXQ

2/5/2020

		HCHS/SOL Field Center		Coordinating Center	HCHS/SOL Operations Committee	HCHS/SOL Steering Committee
1) Unanticipated Problem (UP) Response	Address any ppt. safety issues; inform medical director and PI	Record UP in CDART and notify hchsadverseevent@unc.edu	Report UP to PI and if required, local IRB	Notify NHLBI via the CC	Review study procedures; propose revisions if warranted	Review report of AE and study procedures; modify protocol if required
UP Time / Schedule	Immediate	48 hrs.	72 hrs.	Within 7 calendar days	Within 14 calendar days	Within 30 calendar days
2) Serious Adverse Event (SAE) Response	Address any ppt. safety issues; inform medical director and PI	Record SAE in CDART and notify hchsadverseevent@unc.edu	Report SAE to PI and if required, local IRB	Notify NHLBI via the CC	Review study procedures; propose revisions if warranted	Review report of AE and study procedures; modify protocol if required
SAE Time / Schedule	Immediate	48 hrs.	72 hrs.	Within 7 calendar days	Within 14 calendar days	Within 30 calendar days
3) Minor Adverse Event (MAE) Response	Address any ppt. safety / comfort issues	Record MAE in CDART and notify hchsadverseevent@unc.edu	Report MAE to local IRB if required	Notify NHLBI via the CC	Review study procedures with experts; propose revisions if required	Review report of AE and study procedures; modify protocol if required
MAE Time / Schedule	Immediate	48 hrs.	Within 7 calendar days	Quarterly	Quarterly	Quarterly

HCHS/SOL- Unanticipated Problem (UPR)

QXQ

2/5/2020

4) Anticipated Problem, not an AE Response	Address any ppt. comfort issues	Not reported (not recorded in CDART)	A report to IRB is not required	Report to NHLBI not required	N.A.	N.A.
Anticipated Problem, not an AE Time / Schedule	Immediate	N.A.	N.A.	N.A.	N.A.	N.A.

QxQ Instructions

This is a multiple-occurrence form. Enter a new UPR form for each unanticipated problem event as needed.

A. EVENT INFORMATION – Completed at the HCHS/SOL <u>Field Center</u>

Question 1: Enter the Field Center HCHS/SOL contract number.

Question 2: Enter field center's principal investigator name

Question 3: Enter exam site / field center site name where event occurred

Question 4: Enter date Unanticipated Problem (UP) occurred

Question 5: Whom was the UP reported to:

Question 5a: Indicate if the Principal Investigator at the field site was notified of the UP and if Yes, enter date that person was notified.

Question 5b: Indicate if the field site local IRB was notified of the UP and if Yes, enter date the IRB was notified.

Question 6: Select a source of the event from the selection. Answer choices are:

1=Interview with study participant
2=Blood draw
3=Glucose load
4=Dexa scan
5=MRI scan
6=CT scan
7=Other physical examination or tests
8=Other source

Question 6a: if Other source, specify the source of the event which led to the UP.

Question 7: Describe the UP event by entering a note in CDART. 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. Limit 250 characters.

Question 8: Indicate whether the event is currently:
1=Ongoing
2=Resolved

Question 9: Describe what action was taken as a result of the UP by entering a note in CDART. Limit 250 characters

Question 10: Was this type of event foreseen in the Informed Consent or study Manual of Operations (MOP)?
0=No
1=Yes **[END FORM]**
9=Don't Know

If Yes, END FORM. If No or Don't Know, continue:

Question 11: Likelihood of relationship of the UP to participation in HCHS/SOL **[Answered by site Principal Investigator only]:**

1=Unrelated (clearly not related)
2=Unlikely (doubtful related)
3=Possible (may be related)
4=Probable (likely related)
5=Definite (clearly related)

If needed, please review the OHRP guidance on Unanticipated Problems:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

B. ACTIONS TAKEN BY INVESTIGATORS - Completed by HCHS/SOL Coordinating Center

Question 12: Dates UP was reported:
Question 12a: to NHLBI [MM/DD/YYYY format]
Question 12b: to OSMB [MM/DD/YYYY format]

Question 13: Was a change made to the protocol because of this UP?
0=No
1=Yes

Question 13a: If Yes, date changed [MM/DD/YYYY format]

Question 14: Were any other actions taken by the investigators in response to this UP?
0=No
1=Yes

Question 14a: If Yes, date action taken [MM/DD/YYYY format]

Question 15: If Yes to Questions 13 or 14, specify changes made and/or actions taken. Limit 250 characters.

HCHS/SOL- Unanticipated Problem (UPR)

QXQ

2/5/2020

Question 16 a and b: Enter date this form was completed and CSCC Staff ID code.

[If there is more than one UP to be reported for the same person on a different date, then enter a new occurrence of the UPR form for each one separately]