HCHS/SOL- Minor Adverse Event

QXQ

2/5/2020

General Instructions

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. Adverse events include both physical and psychological harms temporally associated with the individual's participation in the research, whether or not considered related to the subject's participation in the research.
An event is **minor** if it DOES NOT affect a pregnant study participant, a fetus or a newborn, and if it DOES NOT result in any of the following outcomes: Death; A threat to life; Requires (inpatient) hospitalization; Likely causes persistent or significant disability or incapacity; Likely associated with a congenital anomaly or birth defect; or Requires treatment to prevent one of the outcomes listed above, other than for pre-existing conditions detected as a result of participation in HCHS/SOL, its tests and examination protocol.

Minor adverse events (MAEs) are anticipated and can be expected to occur as risks stated in the informed consent and study protocol, and may be study-related, possibly study-related, or not study-related. Refer to the MOP 2 for definitions and details on Adverse Events.

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

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

Notification of the IRB. The HCHS/SOL sIRB (at UNC) does not ask to be notified of MAEs. Completing the MAE form in CDART creates the log of MAEs required by the sIRB. Notification of the field center's local IRB is to be specified by the site IRB. If the local IRB requires notification of a MAE, item 5b 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

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		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
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 MAE form for each minor adverse event as needed.

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

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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 Minor Adverse Event (MAE) occurred

Question 5: Whom was the MAE reported to:

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

Question 5b: Indicate if the field site local IRB was notified of the MAE and if Yes, enter date the local IRB was notified. If notification of the local IRB is not required, or the IRB was not notified, item 5b is left blank.

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, specify the nature of the event which was the source of the MAE.

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

Question 10: Was this type of event foreseen in the Informed Consent or study MOP?

0=No
1=Yes **[END FORM]**
9=Don't Know

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

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Question 11: Likelihood of relationship of the MAE 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)

ACTIONS TAKEN BY INVESTIGATORS - Completed by the HCHS/SOL <u>Coordinating Center</u>

Question 12: Dates MAE 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 MAE?
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 MAE?
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.

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

[If there is more than one MAE to be reported for the same participant, enter a new occurrence of the MAE form for each unique event occurring on a separate day (i.e. a different 24 hour period)]