HCHS/SOL- Serious 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 adverse event is considered **serious** if it affected a pregnant study participant, a fetus or a newborn, or if it results 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, 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. Serious adverse events (SAEs) are therefore unanticipated and unexpected, whether study related or otherwise.

Serious adverse events (SAEs) are not anticipated or foreseen in the study protocol or referred to in the informed consent; they may or may not be related to participation in the study. Refer to Manual of Operations #2 on the field center examination procedures (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. SAEs 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 SAE has been submitted via an email to HchsAdverseEvent@unc.edu.

Notification of the local IRB. Completing the SAE form in CDART allows the CC to notify the sIRB (at UNC) and creates the required log of SAEs. Notification of the field center's local IRB is to be specified by the site IRB. If the local IRB requires notification of a SAE, 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 if actiins 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.

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This could be a multiple-occurrence form if a participant has separate SAEs that each start on different days. Enter a new SAE form for each serious adverse event occurring on a single day (continuous 24 hour period) as needed.

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

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 Serious Adverse Event (SAE) occurred

Question 5: Whom was the SAE reported to:

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

Question 5b: Indicate if the field site local IRB was notified of the SAE 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.