This form was not data entered

Keyed: ( )

SLEEP HEART HEALTH STUDY

Serious Adverse Event Report

Field Site ID: __

Participant ID#: _____

Alpha Code: _____

Date form initiated: __ (month) – __ (day) – 2 0 0 __ (year)

Visit ID Code: F 0 2

Form & revision: S R 2

Form sequence #: __

Instructions: This form is to be completed by the Principal Investigator or Co-Investigator if a serious, unexpected adverse event occurs during or is connected with a SHHS home or clinic visit. Fax completed form to CC and NHLBI within 48 hours of the report of a serious and unexpected adverse event. The following definitions of "serious" and "unexpected" apply:

Serious - A serious adverse event results in death, *or* is life threatening (i.e., the participant was at immediate risk of death), *or* results in disability (substantial disruption of ability to carry out normal functioning), *or* admission to a hospital.

Unexpected - An event is unexpected when the specificity or severity is **not** consistent with the risk information described in the protocol or consent form. *If unsure whether event was unexpected, note uncertainty in item 8 and fax to Coordinating Center and NHLBI Project Officer for review.*

Note: *Any serious, unexpected adverse event noted on this form should also be documented on the AE and AA forms.*

A. Adverse event information

1. Date adverse event reported to field site:

__ (month) – __ (day) – 2 0 0 __ (year)

2. Date adverse event occurred:

__ (month) – __ (day) – 2 0 0 __ (year)

3. Where did the event occur? ***(check one)***

☐ 1 Participant's home

☐ 2 Field site office

☐ 3 Other, *(specify):*

_____

4. Was a SHHS protocol procedure being performed at the time of the adverse event? ***(check one)***

☐ 1 **Yes** ☐ 0 **No** → *Skip to item 5.*

If Yes, which procedure(s)? ***(check all that apply)***

4a. ☐ 1 Physical measurement data collection (e.g., BP, ECG) *(specify)*:

_____

4b. ☐ 1 Interview (e.g., Health Interview, Medications, QOL) *(specify)*:

_____

4c. ☐ 1 During PSG monitor hookup

5. Who observed the adverse event? ***(check all that apply)***

5a. ☐ 1 SHHS personnel *(specify SHHS PIN(s))*: ____ ____ ____ **;** ____ ____ ____

5b. ☐ 1 Participant:

5c. ☐ 1 Participant's family member or other person *(specify relationship)*:

_____

6. Who first reported the event to someone at the SHHS field site office? *(check all that apply)*

6a. ☐ 1 SHHS personnel *(specify SHHS PIN(s))*: ____ ____ ____ ; ____ ____ ____

6b. ☐ 1 Participant:

6c. ☐ 1 Participant's family member or other person *(specify relationship)*:

_____

7. Characterize the adverse event *(check all that apply)*

7a. ☐ 1 Resulted in death:

7b. ☐ 1 Resulted in hospitalization:

7c. ☐ 1 Resulted in disability:

7d. ☐ 1 Was life threatening *(i.e., the participant was at immediate risk of death):*

7e. ☐ 1 Other, *(specify)*:

_____

8. Was the event unexpected? *(check one)*:

☐ 1 Yes

☐ 2 No

☐ 3 Unsure, *(specify reason for uncertainty):*

_____

9. Resolution date *(i.e., first date on which a particular sign or symptom returned to the acceptable range). If there is no resolution by the time the form is faxed to the CC, code as "n-n-n".*

__ __ – __ __ – __ __ __ __
month day year

10. Relationship of adverse event to SHHS procedures *(check one)*:

☐ 1 Event not related to SHHS procedures → *Skip to item 12.*

☐ 2 Remote possibility event was related to SHHS procedures → *Skip to item 12.*

☐ 3 Possible that event was related to SHHS procedures

☐ 4 Probable that event was related to SHHS procedures

☐ 5 Unknown → *Skip to item 12.*

11. Specify procedure(s) related (or suspected to be related) to the adverse event *(e.g., PSG hookup, ECG, AAI)*:

_____

_____

_____

_____

_____

12. Adverse event narrative - Please use this section to further clarify the adverse event. Include discussion of any pre-existing or persistent conditions. Type or print legibly *(attach pages if necessary)*.

B. Assurance of review

13. Printed name of Site Principal Investigator or Co-Investigator completing this form:

_____

14. Signature of Site Principal Investigator or Co-Investigator completing this form:

_____

15. Date signed by Site Principal Investigator or Co-Investigator:

__ __ – __ __ – 2 0 0 __
month day year