Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number   ___ ___ - ___ ___ ___ ___ ___ - ___

Replaced by blinded ID

blind_id	Blinded ID

A2. Acrostic Identifier   ___ ___ ___ ___ ___

Removed to protect privacy

A3. SAE Report Number   ___ ___ ___ ___

EVENTNO	A3. SAE Report Number

A4. Event code from site   ___ ___ ___ ___ ___ ___ ___ ___

CODE_SITE_P	[Added Version B] A4. Event code from site
CODE_SITE	[Version A only] A4. Event code from site

    a. Identify the AE event name/ specify other: _____

CDNAM_SITE	A4a. Identify the AE event name/specify other

A5 Event onset date from site   ___ ___ / ___ ___ / ___ ___ ___ ___
                          M   M   D   D   Y   Y   Y   Y

Replaced by age at onset

onset_age	A5. <created var>Age at onset of event, days

A6. Date reviewed by Medical Monitor   ___ ___ / ___ ___ / ___ ___ ___ ___
                                        M   M   D   D   Y   Y   Y   Y

Replaced by age at review

review_age	A6. <created var>Age at review, days

Section B: ASSESSMENT OF ADVERSE EVENT

B1.   Do you agree with the event code assigned by the site?

YES 1

NO ....2 **(B1a)**

AGREE	B1. Do you agree with the event code/name assigned by the site?
AGREE_C	[Version A only] B1. Do you agree with the code (from code list C)assigned?

    a.   If NO, specify new code: __ __ __ __ __ __ __ __

SPECIFY_P	B1a. Specify new code from code list P
SPECIFY	[Version A only] B1a. If NO, specify new code

    b.   Identify the AE event name/ specify other: _____

EVTNAM_P	[Added version B] B1b. Identify the AE event name from code list P
EVTNAM	[Version A only] B1b. AE event name/specify other
EVTNAM_SITE	[Version A only] B1b_old. OLD AE event name/specify other

B2.   Seriousness of event

NOT SERIOUS.......................................1

MODERATELY SERIOUS 2

SERIOUS 3

DEATH 4

SERIOUS	B2. Seriousness of event

B3.   Was this event expected?

YES...1

NO.. 2

EXPECTED	B3. Was this event expected

B4.   Was this event related to study drug?

NOT RELATED 1

POSSIBLY RELATED............................2

PROBABLY RELATED 3

REL_DRUG	B4. Was this event related to study drug

B5   Was this event related to study test?   NOT RELATED ....1 **(B6)**
                                                         POSSIBLY RELATED 2
                                                       PROBABLY RELATED 3

REL_TEST	B5. Was this event related to study test

      a.   Specify   ECHOCARDIOGRAM………….1

                            NEURODEVELOPMENTAL 2

                            VENIPUNCTURE……………….3

TEST_SPEC	B5a. Specify

B6.   Comments:

_____

_____

_____

COMMENTS	B6. Comments

B7. Date Form finalized: ___ ___ / ___ ___ / ___ ___ ___ ___
                                            M   M   D   D   Y   Y   Y   Y

Replaced by age when form finalized

final_age	B7. <created var>Age when form finalized, days