Section A: KEY IDENTIFYING INFORMATION

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

Replaced by blinded subject ID

subj_id	Blinded subject ID

Blinded site ID <created var>

site_id	Blinded site ID

A2. Acrostic Identifier ___ ___ ___ ___ ___

Removed to protect privacy

A3. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

COMP_AGE	<created var> Age (yrs) of the subject at A3. Date of form completion

A4. Name of person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

Removed to protect privacy

Section B: ADVERSE EVENT SUMMARY

B1. Did patient experience any adverse events since the study consent form was signed?

YES..... 1 NO 2

STOP - FORM COMPLETE

ANYAE	B1. Did patient experience adverse events

B2. Number of adverse events ___ (1-4)

NUMAE	B2. Number of adverse events

Event #1

B3. a. Type of event

VENTRICULAR TACHYCARDIA 1
ATRIAL TACHYCARDIA..... 2
SYNCOPE 3
FALL-INDUCED TRAUMA/BRUISING..... 4
SEVERE ANXIETY..... 5
VENIPUNCTURE BRUISING 6

OTHER.....99

1. If OTHER, specify: _____

_____

TYPEVENT_0	B3a. Type of adverse event (0)
EVNTSPEC_0	B3a1. If other, specify (0)

b. Date of event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

AEDATE_0_AGE	<created var> Age (yrs) of the subject at B3b. Date of adverse event (0)

Event #1 (continued)

c. Was treatment administered for event? YES.....1 NO.....2 (**B3.e**)

AETX_0	B3c. Was treatment administered? (0)

d. Type of treatment

OUTPATIENT, NO INTERVENTION REQUIRED ... 1(**B3.e**)

OUTPATIENT, INTERVENTION REQUIRED 2

INPATIENT 3

1. Specify treatment or intervention administered for event

_____

_____

TXTYPE_0	B3d. Type of treatment (0)
AESPECTX_0	B3d1. Specify treatment (0)

e. Did the event resolve? YES .....1 NO.....2

AERSLV_0	B3e. Did the adverse event resolve? (0)

1. If YES, date event resolved

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

AERSLV_0_AGE	<created var> Age (yrs) of the subject at B3e1. Date adverse event resolved (0)

f. Seriousness of event

NOT SERIOUS 1

MODERATELY SERIOUS 2

SERIOUS..... 3

1. If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event?

YES .....1 NO.....2

COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

SAELEVEL_0	B3f. Seriousness of adverse event (0)
AENOTIFM_0	B3f1. Was a Serious AE Form completed? (0)

g. Was the event associated with a study test?

NOT ASSOCIATED 1

POSSIBLY ASSOCIATED..... 2

PROBABLY ASSOCIATED 3

AEASSOC_0	B3g. Was the adverse event associated with a study test (0)

1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:

ECHOCARDIOGRAM..... 1
CARDIAC MRI..... 2
ELECTROCARDIOGRAM 3
EXERCISE TEST 4
VENIPUNCTURE 5
OTHER..... 99

a. If OTHER, specify: _____

SPECTEST_0	B3g1. Specify test (0)
SPTSTOTH_0	B3g1a. Type of adverse event (0)

FORMSTAT_ID	Unique form/subject ID
FORM_ID	4 letter code for the form
VER_ID	1 letter code added to form code to make unique form/version
DESTATUS	Form completion

Event #2

B4. a. Type of event

VENTRICULAR TACHYCARDIA 1
ATRIAL TACHYCARDIA..... 2
SYNCOPE 3
FALL-INDUCED TRAUMA/BRUISING..... 4
SEVERE ANXIETY..... 5
VENIPUNCTURE BRUISING 6
OTHER.....99

1. If OTHER, specify: _____

_____

b. Date of event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

c. Was treatment administered for event? YES..... 1 NO.....2 (**B4.e**)

d. Type of treatment

OUTPATIENT, NO INTERVENTION REQUIRED ... 1(**B4.e**)
OUTPATIENT, INTERVENTION REQUIRED 2
INPATIENT..... 3

1. Specify treatment or intervention administered for event

_____

_____

e. Did the event resolve? YES .....1 NO.....2

1. If YES, date event resolved

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

f. Seriousness of event

NOT SERIOUS 1
MODERATELY SERIOUS 2
SERIOUS..... 3

1. If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event?

YES .....1 NO.....2

COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

Event #2 (continued)

g. Was the event associated with a study test?

NOT ASSOCIATED 1
POSSIBLY ASSOCIATED 2
PROBABLY ASSOCIATED 3

1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:

ECHOCARDIOGRAM 1
CARDIAC MRI 2
ELECTROCARDIOGRAM 3
EXERCISE TEST 4
VENIPUNCTURE 5
OTHER 99

a. If OTHER, specify: _____

Event #3

B5. a. Type of event

VENTRICULAR TACHYCARDIA 1
ATRIAL TACHYCARDIA 2
SYNCOPE 3
FALL-INDUCED TRAUMA/BRUISING 4
SEVERE ANXIETY 5
VENIPUNCTURE BRUISING 6
OTHER 99

1. If OTHER, specify: _____

_____

b. Date of event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

c. Was treatment administered for event? YES ..... 1 NO 2 (**B5.e**)

Event #3 (continued)

d. Type of treatment

OUTPATIENT, NO INTERVENTION REQUIRED ... 1(**B5.e**)

OUTPATIENT, INTERVENTION REQUIRED 2

INPATIENT 3

1. Specify treatment or intervention administered for event

_____

_____

e. Did the event resolve? YES .....1 NO.....2

1. If YES, date event resolved

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

f. Seriousness of event

NOT SERIOUS 1

MODERATELY SERIOUS 2

SERIOUS..... 3

1. If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event?

YES .....1 NO.....2

COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

g. Was the event associated with a study test?

NOT ASSOCIATED 1

POSSIBLY ASSOCIATED..... 2

PROBABLY ASSOCIATED 3

1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:

ECHOCARDIOGRAM..... 1

CARDIAC MRI..... 2

ELECTROCARDIOGRAM 3

EXERCISE TEST 4

VENIPUNCTURE 5

OTHER..... 99

a. If OTHER, specify: _____

Event #4

B6. a. Type of event

VENTRICULAR TACHYCARDIA 1
ATRIAL TACHYCARDIA..... 2
SYNCOPE 3
FALL-INDUCED TRAUMA/BRUISING..... 4
SEVERE ANXIETY..... 5
VENIPUNCTURE BRUISING 6
OTHER.....99

1. If OTHER, specify: _____

_____

b. Date of event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

c. Was treatment administered for event? YES..... 1 NO.....2 (**B6.e**)

d. Type of treatment

OUTPATIENT, NO INTERVENTION REQUIRED ... 1(**B6.e**)
OUTPATIENT, INTERVENTION REQUIRED 2
INPATIENT 3

1. Specify treatment or intervention administered for event

_____

_____

e. Did the event resolve? YES .....1 NO.....2

1. If YES, date event resolved

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

f. Seriousness of event

NOT SERIOUS 1
MODERATELY SERIOUS 2
SERIOUS..... 3

1. If SERIOUS, was a Serious Adverse Event Notification Form (Form F06B) completed for this event?

YES .....1 NO.....2

COMPLETE SERIOUS ADVERSE EVENT NOTIFICATION FORM (F06B)

Event #4 (continued)

g. Was the event associated with a study test?

NOT ASSOCIATED 1
POSSIBLY ASSOCIATED 2
PROBABLY ASSOCIATED 3

1. If POSSIBLY or PROBABLY ASSOCIATED, specify test:

ECHOCARDIOGRAM 1
CARDIAC MRI 2
ELECTROCARDIOGRAM 3
EXERCISE TEST 4
VENIPUNCTURE 5
OTHER 99

a. If OTHER, specify: _____