INSTRUCTIONS: This form should be completed when a randomized or observation subject permanently withdraws from the SVR Trial.

Section A: KEY IDENTIFYING INFORMATION

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

Replaced by blinded subject ID

blind_id	Blinded ID

A2. Acrostic Identifier ___ ___ ___ ___ ___

Removed to protect privacy

A3. Study visit BASELINE……(0)

VISIT	A3. Study visit

A4. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age (days) at R202 completion

R202_age	<created var>Age at date form completed, days. (A4. COMP_D-DOB)

A5. Name of person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

Removed to protect privacy

Section B: WITHDRAWAL FROM TRIAL

B1. Date of trial withdrawal ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age (days) at trial withdrawal

WDRAW_AGE	<created var>Age at the date of withdrawal, days (B1. WDRAW_D-DOB)

B2. Subject status TRIAL……..1 OBSERVATION……2

STATUS	B2. Subject status

B3. Last visit at which subject completed any trial measures

N/A (NEVER RANDOMIZED) .....-1
BASELINE 0
STUDY VISIT 1 (Norwood) 1
STUDY VISIT 2 (Stage II) 2
STUDY VISIT 3 (12 months) 3
STUDY VISIT 4 (14 months) 4
STUDY VISIT 5 (2 years) 5
STUDY VISIT 6 (3 years) 6

STUDY VISIT 7 (4 years) 7
STUDY VISIT 8 (5 years) 8

LASTVIS	B3. Last visit at which subject completed any trial measures?

B4. Date subject last seen for trial ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age (days) of the subject last seen for trial

LAST_AGE	<created var>Age at the date subject last seen for trial, days. (B4. LAST_D-DOB)

B5. Primary indication for withdrawal from trial

FAMILY WITHDREW PATIENT FROM TRIAL .....1 **(B7)**
PHYSICIAN WITHDREW PATIENT FROM TRIAL .....2 **(B7)**
PATIENT LOST TO FOLLOW-UP .....3 **(B7)**
PATIENT DEATH .....4 **(B7)**
OTHER .....99 **(B7)**

a. OTHER, specify _____

WDRAW_R	B5. Primary indication for withdrawal
WDRAW_S	B5a. OTHER, specify

NOTE:
Question B6 is no longer applicable and will be SKIPPED for all subjects.

~~B6.~~ Was consent provided for the subject to be followed in the Observation cohort? YES……....1 NO……...2 NOT APPLICABLE…..…-1

OBSERV	B6. Will the patient be followed in the observation cohort?

B7. Comments (optional) _____
_____
_____
_____
_____
_____
_____
_____
_____

R202COMM	B7. Comments (optional)

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

END OF FORM