

**INSTRUCTIONS:** This form should be completed if a patient will not be completing any remaining study visits. It should be entered into the Baseline Event in the ADEPT system.

**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. Date of study withdrawal \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
M M / D D / Y Y Y Y

**Replaced by age at study withdrawal**

withdr_age	A3. <created var>Age at study withdrawal, days
------------	--

A4. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
M M / D D / Y Y Y Y

**Replaced by age at form completion**

comp_age	A4. <created var>Age at form completion, days
----------	---

A5. Name of person completing form \_\_\_\_\_  
PRINT FULL NAME INITIALS

**Removed to protect privacy**

**Section B: FINAL GROWTH MEASUREMENTS AT WITHDRAWAL**

**If patient is being withdrawn from the study during a regularly scheduled study visit, and his/her growth measurements have already been taken and recorded on Form S106, there is no need to complete B3-B5 below.**

B1. Is withdrawal occurring at a regular study visit? YES ..... 1 **(C1)** NO ..... 2

GM_NEED	B1. Is withdrawal occurring at a regular study visit?
---------	---

B2. Is patient available for growth measurements at time of withdrawal? YES ..... 1 NO ..... 2 **(C1)**

GM_AVAIL	B2. Is patient available for growth measurements
----------	--

**INSTRUCTIONS: If Measures 1 and 2 for questions B3, B4 and B5 differ by more than the stated amount in the “Absolute Difference” column, a third measurement must be taken.**

	a. <u>Measure 1</u>	b. <u>Measure 2</u>	<u>Absolute Difference</u>	c. <u>Measure 3</u>
B3. Weight (kg)	___ . ___	___ . ___	<b>&gt; 0.1 kg →</b>	___ . ___

WT1_WTHD	B3a. Weight: Measure 1 (kg)
WT2_WTHD	B3b. Weight: Measure 2 (kg)
WT3_WTHD	B3c. Weight: Measure 3 (kg), if  WT1_WTHD-WT2_WTHD >0.1 kg

B4. Length (cm)	___ . ___	___ . ___	<b>&gt; 1.0 cm →</b>	___ . ___
-----------------	-----------	-----------	----------------------	-----------

HT1_WTHD	B4a. Length: Measure 1 (cm)
HT2_WTHD	B4b. Length: Measure 2 (cm)
HT3_WTHD	B4c. Length: Measure 3 (cm), if  HT1_WTHD-HT2_WTHD >1.0 cm

B5. Head circumference (cm)	___ . ___	___ . ___	<b>&gt; 0.2 cm →</b>	___ . ___
-----------------------------	-----------	-----------	----------------------	-----------

HC1_WTHD	B5a. Head circumference: Measure 1 (cm)
HC2_WTHD	B5b. Head circumference: Measure 2 (cm)
HC3_WTHD	B5c. Head circumference: Measure 3 (cm), if  HC1_WTHD-HC2_WTHD >0.2 cm

**Section C: WITHDRAWAL FROM TRIAL**

C1. Last visit at which patient completed any study measures

- BASELINE ..... 0
- STUDY VISIT 1 (Day 4)..... 1
- STUDY VISIT 2 (Week 2) ..... 2
- STUDY VISIT 3 (Pre-Glenn) ..... 3
- STUDY VISIT 4 (Restart)..... 4
- STUDY VISIT 5 (Age 10 mo.) ..... 5

LASTV204	C1. Last visit at which patient completed any study measures
----------	--

C2. Date patient last seen for trial          /     /     /     /     /     /     /    

M   M   D   D   Y   Y   Y   Y

**Replaced by age when patient last seen for trial**

lstsn_age	C2. <created var>Age when patient last seen for trial, days
-----------	---

C3. Primary indication for withdrawal from trial (circle the most specific reason listed)

- FAMILY WITHDREW PATIENT FROM TRIAL ..... 1
- PHYSICIAN WITHDREW PATIENT FROM TRIAL..... 2
- PATIENT LOST TO FOLLOW-UP ..... 3
- PATIENT DEATH ..... 4
- OPEN-LABEL USE OF ACE INHIBITOR..... 5
- HEART TRANSPLANT ..... 6
- OTHER..... 99

a. Specify OTHER \_\_\_\_\_

WITHDR_R	C3. Indication for withdrawal from trial
WITHDR_S	C3a. Specify Other reason for withdrawal from trial

C4. Date last dose of study drug taken          /     /     /     /     /     /     /    

M   M   D   D   Y   Y   Y   Y

**Replaced by age when last dose of study drug taken**

wlstdr_age	C4. <created var>Age at last dose of study drug, days
------------	---

C5. Last dosage of study drug administered \_\_\_\_\_ . \_\_\_\_\_ mg BID

WLSTDOSE	C5. Last dosage of study drug administered, mg BID
----------	--

C6. Comments \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

COMMS204	C6. Comments
----------	--------------