

**INSTRUCTIONS:** This form must be completed for all trial subjects after 24-hour ambulatory ECG collected at trial visits. 24-hour ECGs associated with study drug dose uptitrations/down-titrations will be captured on the dose adjustment forms. Only complete this form if:

- There are ≥ 20 hours of useable data on the 24-hour ECG at Baseline, or
- There are ≥ 20 hours of useable data on the 24-hour ECG at the end of up-titration or study visits 1, 2, 3, or 4 *unless* the subject has been randomized to study drug B (losartan).

**Section A: KEY IDENTIFYING INFORMATION**

A1. Study Identification Number \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

A2. Study visit

BASELINE ..... 0

STUDY VISIT 1 (Month 6) ..... 1 **(A3)**

STUDY VISIT 2 (Month 12) ..... 2 **(A3)**

STUDY VISIT 3 (Month 24) ..... 3 **(A3)**

STUDY VISIT 4 (Month 36) ..... 4 **(A3)**

END OF UPTITRATION ..... 6 **(A3)**

a. What number screening is this? \_\_\_\_\_

A3. Date of form completion

\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M D D Y Y Y Y

A4. Name of person completing form

\_\_\_\_\_  
 PRINT FULL NAME INITIALS

**Answer question A5 for the baseline visit only. If this is NOT the baseline visit, skip question A5 and go to section B.**

A5. Did the subject successfully complete the wash-out protocol?

YES ..... 1

NOT APPLICABLE ..... -1 **(B1)**

a. Date when the last dose was taken during the wash-out protocol

\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M D D Y Y Y Y

**Section B: ELECTROCARDIOGRAM RESULTS**

B1. Date 24-hr ECG **started**                                 \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
   M   M     /   D   D     /   Y   Y   Y   Y

B2. Date 24-hr ECG **completed**                                 \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  
   M   M     /   D   D     /   Y   Y   Y   Y

B3. Are there ≥ 20 hours of useable data on the 24-hr ECG?      YES..... 1                      NO.....2\*

\*If **NO** and A2=0 (baseline study visit), then 24-hour ECG must be redone for the study subject. If **NO** and not baseline study visit, 24-hr ECG must be redone, *unless* subject is randomized to study drug B (losartan)

B4. **Average** 24-hr heart rate                                 \_\_\_ \_\_\_ \_\_\_ beats/min

B5. Is 24-hr average heart rate above threshold for age?  
       • ≥ 60 BPM if <12 months                                 YES..... 1                      NO.....2\*  
       • ≥ 55 BPM if 12 – 24 months of age  
       • ≥ 50 BPM if >24 months of age

\*If **NO**, 24-hr ECG must be scanned

**Section Z: TIME TO COMPLETE FORM**

Z1. How long did it take to complete this form?     \_\_\_ \_\_\_ \_\_\_ minutes

**END OF FORM**