INSTRUCTIONS: Complete this form at the time of study drug initiation. This form is addable in the dose adjustment cycle event.

Section A: KEY IDENTIFYING INFORMATION

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

A2. Study drug assigned
STUDY DRUG A 1
STUDY DRUG B 2

A3. Prescription number 0 0 1

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

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

Baseline 24 hour average heart rate* ___ ___ ___ BPM (form A113)

***24-hr ECG results must be verified BEFORE starting study drug. Once average baseline heart rate is obtained and recorded on form A113, the Coordinator may telephone the subject/family and instruct them on how to take the initial dose and complete the first cycle.**

Section B: STUDY DRUG INITIATION

B1. Date of initial dose (Rx date) ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Subject weight ___ ___ ___ . ___ kg (form A120)

B2. Dose prescribed ___ . ___ mg/kg

B3. Study drug administration DAILY 1

B4. Dose to administer per day ___ ___ ___ . ___ mg/day

If the subject was randomized to study drug A, continue to question C1, otherwise, if the subject was randomized to study drug B, skip to question Z1.

Between day 6 and 8, the Study Coordinator must contact the subject or primary caregiver to assess drug tolerance.

Section C: SAFETY ASSESSMENT

C1. Date of check-up call ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C2. Is subject reporting any drug intolerances? YES .....1 NO.....2 **(D1)**

Record all intolerances reported by subject/parent. Be certain to provide answers to ALL questions listed (a-f).

		YES	NO
a.	Dizziness interfering with activities of daily living	1	2
b.	Fatigue interfering with activities of daily living	1	2
c.	Syncope	1	2
d.	Shortness of breath interfering with activities or new shortness of breath	1	2
e.	Other symptoms interfering with activities of daily living i. Specify: _____	1	2 (C2f)
f.	Other reason for not increasing dose i. Specify: _____	1	2 (D1)

If the subject is tolerating the current dose with no reported intolerances, the dose may be uptitrated. If the subject is reporting intolerances to the study drug, the prescribing investigator should consider adjusting the dose (night-time administration or b.i.d. administration of the current dose).

Section D: ASSESSMENT OUTCOME

D1. What is the outcome of the above assessment?

CONTINUE UPTITRATION .....1 **(E1)**
ADJUST DOSE.....2 **(F1)**

Section E: STUDY DRUG UPTITRATION

E1. Date of uptitration (Date Rx was changed) ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Previous dose administered
(report DAILY dose from previous cycle) ___ ___ ___ . ___ mg (See Section B)

Subject weight ___ ___ ___ . ___ kg (See Section B)

E2. Dose prescribed ___ . ___ mg/kg
(Enter '-5' if subject at MAX dose of study drug)

E3. Study drug administration DAILY 1

E4. Dose to administer per day ___ ___ ___ . ___ mg/day **(Z1)**

Section F: STUDY DRUG DOSE ADJUSTMENT

F1. Date of adjustment (Date Rx was changed) ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

F2. Action taken by study investigators

CHANGED TO NIGHT-TIME ADMINISTRATION ..... 1 **(F3)**

CHANGED TO TWICE-A-DAY ADMINISTRATION ..... 2 **(F3)**

DECREASE CURRENT DOSE ..... 3 **(F3)**

MAINTAIN CURRENT DOSE ..... 4 **(F3)**

PERMANENTLY DISCONTINUED STUDY DRUG ..... 5 **(Z1)**
(Please complete A212)

OTHER 99

a. Specify: _____

F3. New/current dose prescribed ___ . ___ mg/kg

F4. New/current dose to administer per day ___ ___ ___ . ___ mg/day

Section Z: TIME TO COMPLETE FORM

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

END OF FORM

REMINDER: On day 21 and before day 28 of Cycle 1b, the Study Coordinator must:

1. **Contact each subject (or parent) to verify the presence or absence of drug intolerances and to change the drug dose.**
2. **Mail the 24-hr ECG. 24-hr ECG must be mailed such that the subject or family has it by day 21. The subject or family should be encouraged to obtain the 24-hr ECG ASAP (may be worn on a school day) and then to return ASAP. The 24-hr ECG should be started on Day 21, 22, or 23.**
3. **Remind the parent of subjects <18 months of age that a blood pressure (BP) must be measured at the PHN center or by local physician. If BP measure taken outside PHN center, documentation must be provided to the study investigator BEFORE any increase in study drug can occur. BP should be measured on Day 21, 22, or 23.**
   a. **If the BP measure is <2%tile for age, the subject must be recalled to the PHN center for evaluation.**
4. **For any subject <18 months of age, a safety laboratory assessment must be completed at the end of cycle 1 (see form A122). Safety laboratory results MUST be documented on form A112 (Safety Laboratory Findings). Blood should be drawn on Day 21, 22, or 23.**