PEDS-C
Untreated Follow-Up Assessment Summary
Follow-Up Week 4

20457

Please Use Black Pen To Fill Out Form.

Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix Correction

Instructions

Use this form for all therapy groups .

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No uf4patcont

B. If **No**, date of the Withdrawal/Close-out Form: uf4wddt (mm / dd / yyyy)

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam form been completed? ○ Yes ○ No uf4physexm

B. If **Yes**, date of the form: uf4physexmdt (mm / dd / yyyy)

Concurrent Medications and Conditions

3.A. *Ask the parent (or patient) the following question:* Has your child (have you) had any other problems since your last visit? ○ Yes ○ No uf4patprob

If **No**, skip to item 4.

B. Was a Concurrent Medical Condition Form completed? ○ Yes ○ No uf4medcon

C. If **Yes**, date of the form: uf4medcondt (mm / dd / yyyy)

D. Was a Serious Adverse Event Form completed? ○ Yes ○ No uf4sae

E. If **Yes**, date of the SAE form: uf4saedt (mm / dd / yyyy)

F. Was an Adverse Event Form completed? ○ Yes ○ No uf4ae

G. If **Yes**, date of the AE form: uf4aedt (mm / dd / yyyy)

4.A. *Ask the parent (or patient) the following question:* Has your child (have you) taken any new medicines, other than those given to you within this study, since the last visit? ○ Yes ○ No uf4newmed

If **No**, skip to item 5.

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No uf4meds

C. If **Yes**, date of the form: uf4medsdt (mm / dd / yyyy)

Signature: _____ **Certif. #:** staffid1 -

PEDS-C
Untreated Follow-Up Assessment Summary
Follow-Up Week 4

29906

Please Use Black Pen To Fill Out Form.

Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix ○ Correction

Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age? ○ Yes ○ No uf4fem

If **No**, skip to item 6.

B. Was a serum pregnancy test done? ○ Yes ○ No uf4srmptst

If **No**, skip to item 7.

C. Date of the test: uf4srmptstdt (mm / dd / yyyy)

D. Serum pregnancy test result: ○ Positive ○ Negative uf4srmptstres

E. If **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ○ Yes ○ No uf4pregrep

6.A. Is the patient a sexually active male? ○ Yes ○ No uf4sexactm

If **No**, skip to item 7.

B. Is his sexual partner pregnant? ○ Yes ○ No uf4mppreg

C. If **Yes**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ○ Yes ○ No uf4pmregrep

Patient Study Drug Therapy

7. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No uf4meddry

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No uf4tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: uf4tdadt (mm / dd / yyyy)

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No uf4thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: uf4thrstpdt (mm / dd / yyyy)

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No uf4misdos

B. If **Yes**, date of the Therapy Missed Dose Form: uf4misdosdt (mm / dd / yyyy)

List of Laboratory Tests Ordered at Follow-Up Week 4

11.A. Hematology: Done ○ Unable to obtain ○ uf4hmtotst

B. Chemistry / Pregnancy: Done ○ Unable to obtain ○ uf4chemtst

Signature: _____ **Certif. #:** staffid2 -