

Untreated Follow-Up Assessment Summary
Follow-Up Week 8

9798

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
	mm / dd / yyyy	- - -		

Instructions

Use this form for all therapy groups .

1.A. Is the patient willing and able to continue in the study?

Yes No *uf8patcont*

B. If **No**, date of the Withdrawal/Close-out Form:

uf8wdt / /
mm dd yyyy

CRA Use Only

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam form been completed?

Yes No *uf8physexm*

B. If **Yes**, date of the form:

uf8physexmdt / /
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 *uf8patprob*

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

B. Was a Concurrent Medical Condition Form completed?

Yes No *uf8medcon*

C. If **Yes**, date of the form:

uf8medcondt / /
mm dd yyyy

D. Was a Serious Adverse Event Form completed?

Yes No *uf8sae*

E. If **Yes**, date of the SAE form:

uf8saedt / /
mm dd yyyy

F. Was an Adverse Event Form completed?

Yes No *uf8ae*

G. If **Yes**, date of the AE form:

uf8aedt / /
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 *uf8newmed*

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

B. Has the Concurrent Medications Form been completed?

Yes No *uf8meds*

C. If **Yes**, date of the form:

uf8medsdt / /
mm dd yyyy

Signature: _____

Certif. #: _____

staffid1 -

PEDS-C

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PDC 63
Rev 0
02/17/2005
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	mm / dd / yyyy	- - - -		

Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age?

Yes No *uf8fem*

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

B. Was a serum pregnancy test done?

Yes No *uf8srmpst*

If **No**, skip to item Signature and Certif. #.

C. Date of the test:

uf8srmpstdt
mm / dd / yyyy

D. Serum pregnancy test result:

Positive Negative *uf8srmpstres*

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 *uf8pregrep*

6.A. Is the patient a sexually active male?

Yes No *uf8sexactm*

If **No**, skip to item Signature and Certif. #.

B. Is his sexual partner pregnant?

Yes No *uf8mppreg*

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 *uf8pmregrep*

Signature: _____

Certif. #: [] [] - [] [] [] []