



54536

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>	Correction <i>corrfix</i>
[][][]	[][] / [][] / [][][][] <small>mm dd yyyy</small>	[][] - [][][] - [][]	[][][]	<input type="checkbox"/>

Instructions

Use this form for all therapy groups .

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

Yes No *u16ptcnt*

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

u16wddt [][] / [][] / [][][][]
mm dd yyyy

CRA Use Only

Concurrent Medications and Conditions

2.A. Ask the parent (or patient) the following question:
Has your child (have you) had any other problems since your last visit?

Yes No *u16ptprb*

If **No**, skip to item 3.

B. Was a Concurrent Medical Condition Form completed?

Yes No *u16mdcon*

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

u16mdcdt [][] / [][] / [][][][]
mm dd yyyy

D. Was a Serious Adverse Event Form completed?

Yes No *u16sae*

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

u16saedt [][] / [][] / [][][][]
mm dd yyyy

F. Was an Adverse Event Form completed?

Yes No *u16ae*

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

u16aedt [][] / [][] / [][][][]
mm dd yyyy

3.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 *u16nwmed*

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

B. Has the Concurrent Medications Form been completed?

Yes No *u16meds*

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

u16mstdt [][] / [][] / [][][][]
mm dd yyyy

Signature: _____

Certif. #:

staffid1 [][] - [][][]

Follow-Up Week 16 Telephone

3501

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	- - - - -		

Concurrent Medications and Conditions (Continued)

CRA Use Only

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

Yes No *u16fem*

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

B. What was the first day of her last menstrual period?

u16mnsdt mm / dd / yyyy NA *u16mnsna*

C. Does she show secondary amenorrhea of 1 week or more?

Yes No NA *u16amnor*

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

D. Was a urine pregnancy test done?

Yes No *u16upgst*

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

E. Date of the test:

u16upgdt mm / dd / yyyy

F. Urine pregnancy test result:

Positive Negative *u16upgrs*

If **Negative**, skip to item 5.

G. Was a serum pregnancy test done?

Yes No *u16spgst*

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

H. Date of the test:

u16spgdt mm / dd / yyyy

I. Serum pregnancy test result:

Positive Negative *u16spgrs*

J. If either the urine or serum test was **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours?

Yes No *u16pgrep*

Signature: _____

Certif. #: *staffid2* - [] [] [] []

29333

Please Use Black Pen To Fill Out Form.

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

Concurrent Medications and Conditions (Continued)

5. Is the patient a sexually active female at least 10 years old or a sexually active male?

Yes	No
<input type="radio"/>	<input type="radio"/> <i>u16sexat</i>

CRA Use Only

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

6. Indicate all types of contraception used (Answer each item):

A. Oral contraceptive	<input type="radio"/> <input type="radio"/> <i>u16cnora</i>
B. Intrauterine contraceptive device	<input type="radio"/> <input type="radio"/> <i>u16cniud</i>
C. Depot contraceptives (implants, injectables)	<input type="radio"/> <input type="radio"/> <i>u16cndep</i>
D. Physical barrier (condom, diaphragm)	<input type="radio"/> <input type="radio"/> <i>u16cnphy</i>
E. Abstinence	<input type="radio"/> <input type="radio"/> <i>u16cnabs</i>
F. None	<input type="radio"/> <input type="radio"/> <i>u16cnnon</i>
G. Other	<input type="radio"/> <input type="radio"/> <i>u16cnoth</i>
Specify <i>u16cnosp</i>	

Signature: _____

Certif. #:	<i>staffid3</i> -
-------------------	-------------------