

27541

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	<input type="radio"/> Correction
<div> <div></div> <div></div> <div></div> </div>	<div> <div></div> <div></div> </div> / <div> <div></div> <div></div> </div> / <div> <div></div> <div></div> <div></div> <div></div> </div> <div>mm</div> <div>dd</div> <div>yyyy</div>	<div> <div></div> <div></div> </div> - <div> <div></div> <div></div> <div></div> </div> - <div> <div></div> </div>	<div> <div></div> <div></div> <div></div> </div>	

**Instructions**

Use this form for all therapy groups .

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

☐ Yes ☐ No

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

 / 
  / 
 

mm

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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

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

B. Was a Concurrent Medical Condition Form completed?

☐ Yes ☐ No

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

 / 
  / 
 

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D. Was a Serious Adverse Event Form completed?

☐ Yes ☐ No

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

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F. Was an Adverse Event Form completed?

☐ Yes ☐ No

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

 / 
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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

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

B. Has the Concurrent Medications Form been completed?

☐ Yes ☐ No

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

 / 
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Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

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# PEDS-C

## Untreated Follow-Up Assessment Summary

### Follow-Up Week 20 Telephone

PDC 66  
Rev 1  
08/22/2006  
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Please Use Black Pen To Fill Out Form.

<b>Week #</b>	<b>Date of Assessment</b>	<b>Patient ID</b>	<b>Patient Letter Code</b>	
<div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div>	<div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> / <div style="border: 1px solid black; width: 60px; height: 30px; display: inline-block;"></div>	<div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div>	<div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 30px; height: 30px; display: inline-block;"></div>	<input style="width: 10px; height: 10px;" type="radio"/> <b>Correction</b>
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#### Concurrent Medications and Conditions (Continued)

**CRA Use Only**

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

☐ Yes    ☐ No

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

B. Was a urine pregnancy test done?

☐ Yes    ☐ No

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

C. Date of the test:

mm

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yyyy

D. Urine pregnancy test result:

☐ Positive    ☐ Negative

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

E. Was a serum pregnancy test done?

☐ Yes    ☐ No

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

F. Date of the test:

mm

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G. Serum pregnancy test result:

☐ Positive    ☐ Negative

H. 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

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

**Yes**    **No**  
☐    ☐

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"/> |
| B. Intrauterine contraceptive device            | <input type="radio"/> | <input type="radio"/> |
| C. Depot contraceptives (implants, injectables) | <input type="radio"/> | <input type="radio"/> |
| D. Physical barrier (condom, diaphragm)         | <input type="radio"/> | <input type="radio"/> |
| E. Abstinence                                   | <input type="radio"/> | <input type="radio"/> |
| F. None   | <input type="radio"/> | <input type="radio"/> |
| G. Other  | <input type="radio"/> | <input type="radio"/> |

Specify

**Signature:** \_\_\_\_\_

**Certif. #:**

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