



37381

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 .

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

Yes No *u24ptcnt*

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

u24wddt
mm / dd / yyyy

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Vital Signs

2.A. Temperature: *u24tmp* °C

2.B. Site: Oral Tympanic Axillary Unable to obtain *u24tmpst*

3. Blood Pressure: A. Systolic *u24sysbp* mmHg

B. Diastolic *u24diabp* mmHg Unable to obtain *u24bpna*

4. Pulse: *u24puls* bpm Unable to obtain *u24pulna*

Physical Exam

5. Is the indicated body area within normal limits? Specify or comment if the response is No.

1. Yes No 2. Specify / Comment

A. Head, eyes, ears: *u24head*

B. Nose, mouth, throat: *u24nose*

C. Neck: *u24neck*

D. Chest (including breasts, axillae): *u24chst*

E. Genitalia, groin, buttocks: *u24gntl*

F. Abdomen: *u24abdm*

G. Each extremity: *u24extm*

H. Back, including spine: *u24back*

I. Skin: *u24skin*

Signature: _____

Certif. #: *staffid1* - [] [] [] []

PEDS-C

Untreated Follow-Up Assessment Summary

Follow-Up Week 24

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mm	/ dd / yyyy	- - - - -	- - -	

Physical Exam (Continued)

CRA Use Only

6. Is the indicated organ system within normal limits? Specify or comment if the response is **No**.

1. Yes No 2. Specify

- A. Neurologic: *u24neur*

- B. Psychologic: *u24psyc*

- C. Genitourinary: *u24gnto*

- D. Hematologic / Lymphatic: *u24hmto*

- E. Allergies / Immunologic: *u24allr*

- F. Musculoskeletal: *u24musc*

- G. Other: *u24othog*

7.A. Is the patient a sexually active female over the age of 10 or a sexually active male? Yes No

u24sexat

If **No**, skip to item 8.

B. Indicate ALL types of contraception used (Answer each item):

- 1. Oral contraceptive: *u24cnora*
- 2. Intrauterine contraceptive device: *u24cniud*
- 3. Depot contraceptives (Implants, injectables): *u24cndep*
- 4. Physical barrier (condom, diaphragm) *u24cnphy*
- 5. Abstinence: *u24cnabs*
- 6. None: *u24cnnon*
- 7. Other: *u24cnoth*

Specify *u24cnosp*

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Certif. #: *staffid2* - - - - -

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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
[][]	[][] / [][] / [][][][] <small>mm dd yyyy</small>	[][] - [][][][] - [][]	[][][]	[][][]

Anthropometry

A. First measurement B. Second measurement C. Unable to measure

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8. Height:	<input type="text" value="u24ht1"/> [][] . [][] cm	<input type="text" value="u24ht2"/> [][] . [][] cm	<input type="radio"/> <input type="text" value="u24htna"/>	
9. Weight:	<input type="text" value="u24wt1"/> [][] . [][] kg	<input type="text" value="u24wt2"/> [][] . [][] kg	<input type="radio"/> <input type="text" value="u24wtna"/>	
10. Mid-arm circumference (right):	<input type="text" value="u24arm1"/> [][] . [][] cm	<input type="text" value="u24arm2"/> [][] . [][] cm	<input type="radio"/> <input type="text" value="u24armna"/>	
11. Biceps skinfold: (right):	<input type="text" value="u24bskn1"/> [][] . [][] mm	<input type="text" value="u24bskn2"/> [][] . [][] mm	<input type="radio"/> <input type="text" value="u24bskna"/>	
12. Triceps skinfold: (right):	<input type="text" value="u24tskn1"/> [][] . [][] mm	<input type="text" value="u24tskn2"/> [][] . [][] mm	<input type="radio"/> <input type="text" value="u24tskna"/>	
13. Subscapular skinfold: (right):	<input type="text" value="u24sskn1"/> [][] . [][] mm	<input type="text" value="u24sskn2"/> [][] . [][] mm	<input type="radio"/> <input type="text" value="u24sskna"/>	
14. Iliac skinfold: (right):	<input type="text" value="u24iskn1"/> [][] . [][] mm	<input type="text" value="u24iskn2"/> [][] . [][] mm	<input type="radio"/> <input type="text" value="u24iskna"/>	
15.A. Has a DXA scan been performed?	<input type="radio"/> Yes <input type="radio"/> No <input type="text" value="u24dxa"/>			
B. If Yes, date of scan:	<input type="text" value="u24dxadt"/> [][] / [][] / [][][][] <small>mm dd yyyy</small>			
16.A. Has a Bio-electrical Impedance Analysis been performed?	<input type="radio"/> Yes <input type="radio"/> No <input type="text" value="u24bia"/>			
B. If Yes, date of BIA:	<input type="text" value="u24biadt"/> [][] / [][] / [][][][] <small>mm dd yyyy</small>			
17.A. Has the parent / patient been given the 3-day food diary?	<input type="radio"/> Yes <input type="radio"/> No <input type="text" value="u24fdry"/>			
B. If Yes, date of first diary day:	<input type="text" value="u24fdrdt"/> [][] / [][] / [][][][] <small>mm dd yyyy</small>			
18.A. Has the Physical Activity Assessment been completed?	<input type="radio"/> Yes <input type="radio"/> No <input type="text" value="u24pact"/>			
B. If Yes, date completed:	<input type="text" value="u24pacdt"/> [][] / [][] / [][][][] <small>mm dd yyyy</small>			

Signature: _____

Certif. #: _____

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Week #
week
[][][]

Date of Assessment
assessdft
[][] / [][] / [][][][]
mm dd yyyy

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Concurrent Medication and Conditions

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

Yes No **u24ptprb**

If No, skip to item 20.

B. Was a Concurrent Medical Conditions form completed?

Yes No **u24mdcon**

1. If Yes, date of the form:

u24mdcddt
[][] / [][] / [][][][]
mm dd yyyy

C. Was a Serious Adverse Event form completed?

Yes No **u24sae**

1. If Yes, date of SAE form:

u24saedt
[][] / [][] / [][][][]
mm dd yyyy

D. Was an Adverse Event form completed?

Yes No **u24ae**

1. If Yes, date of AE form:

u24aedt
[][] / [][] / [][][][]
mm dd yyyy

20.A. Ask the parent (or patient) the following question:
"Has child (have you) taken any new medicines, other than those given to you within this study, since the last visit?"

Yes No **u24nwmed**

If No, skip to item 21.

B. Was a Concurrent Medications form completed?

Yes No **u24meds**

1. If Yes, date of the form:

u24mdsdt
[][] / [][] / [][][][]
mm dd yyyy

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

Yes No **u24fem**

If No, skip to item 22.

B. Has a serum pregnancy test been done?

Yes No **u24spgst**

If No, skip to item 23.

C. Date of the serum test:

u24spgdt
[][] / [][] / [][][][]
mm dd yyyy

D. Serum pregnancy test result:

Positive Negative **u24spgrs**

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 **u24pgrep**

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<i>week</i>	<i>assessdt</i> <small>mm / dd / yyyy</small>	<i>idn</i> - -	<i>letcode</i>	<i>corrfix</i> Correction

Concurrent Medication and Conditions (Continued)

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

Yes No *u24xactm*

If **No**, skip to item 23.

B. Is his sexual partner pregnant?

Yes No *u24mpreg*

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 *u24mprep*

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Depression Screen

23.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D?

Yes No *u24cdi19*

If **No**, skip to item 24.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements?

Yes No *u24refdp*

If **Yes**, begin a Depression Management Tracking Form.

Laboratory Tests Ordered at Follow-Up Week 24

	Done	Unable to obtain
24.A. Hematology:	<input type="radio"/>	<input type="radio"/> <i>u24hmtst</i>
B. PT/PTT:	<input type="radio"/>	<input type="radio"/> <i>u24ptst</i>
C. Chemistry / Pregnancy:	<input type="radio"/>	<input type="radio"/> <i>u24chmst</i>
D. HCV - RNA (Clinical):	<input type="radio"/>	<input type="radio"/> <i>u24vlcst</i>
E. HCV - RNA (Research):	<input type="radio"/>	<input type="radio"/> <i>u24vlrst</i>
F. Thyroid function:	<input type="radio"/>	<input type="radio"/> <i>u24thyst</i>
G. Serum bank:	<input type="radio"/>	<input type="radio"/> <i>u24serbk</i>
H. Urinalysis:	<input type="radio"/>	<input type="radio"/> <i>u24urnst</i>

Signature: _____

Certif. #:

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week	assessdt	idn	letcode	correct
	mm / dd / yyyy	- - - -		Correction

Quality of Life Tests Administered at Week 24

Test Name	1. Completed		2. Form date			3. Completed by	
	Yes	No	mm	dd	yyyy	Patient	Parent
25.A. CHQ (Patient)	u24cht <input type="radio"/>	<input type="radio"/>	u24chtdt	/	/	u24chtby	
B. CHQ (Parent)	u24chr <input type="radio"/>	<input type="radio"/>	u24chrdt	/	/	u24chrby	
C. BRIEF (Parent)	u24brf <input type="radio"/>	<input type="radio"/>	u24brfdt	/	/	u24brfby	
D. CBCL (Parent)	u24cbc <input type="radio"/>	<input type="radio"/>	u24cbcdt	/	/	u24cbcby	
E. ABCL (Parent)	u24abc <input type="radio"/>	<input type="radio"/>	u24abcdt	/	/	u24abcby	
F. LEC (Parent)	u24lec <input type="radio"/>	<input type="radio"/>	u24lecdt	/	/	u24lecby	
G. SF-36 (Parent)	u24s36 <input type="radio"/>	<input type="radio"/>	u24s36dt	/	/	u24s36by	

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Signature: _____

Certif. #:

staffid6	-				
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