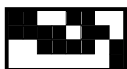


PEDS-C Baseline Assessment

PDC 10
Rev 0
12/17/2004
Page 1 of 5



63037

Please Use Black Pen To Fill Out Form.

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

Instructions

Use this form at the Baseline Visit for patients in all therapy groups who have been screened and randomized.

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

Yes No
 blpatcon

CRA Use Only

If **Yes**, skip to item 2.

B. If **No**, Date of Withdrawal / Close-out

blwddt / mm / dd / yyyy

Skip to Signature and Staff ID # at the bottom of THIS page.
Do NOT complete the remaining pages of this form.

Vital Signs and Symptom Directed Physical

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

Yes No
 blpexm

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

blpexmdt / mm / dd / yyyy

Anthropometry

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

3. Height:

blht1 . cm

blht2 . cm

blhtna

4. Weight:

blwt1 . kg

blwt2 . kg

blwtna

5. Mid-arm circumference (right):

blarm1 . cm

blarm2 . cm

blarmna

6. Biceps skinfold: (right):

blbskn1 . mm

blbskn2 . mm

blbsknna

7. Triceps skinfold: (right):

bltskn1 . mm

bltskn2 . mm

bltsknna

8. Subscapular skinfold: (right):

blsskn1 . mm

blsskn2 . mm

blssknna

9. Iliac skinfold: (right):

bliskn1 . mm

bliskn2 . mm

blisknna

Signature: _____

Certif. #: **staffid1** - -

PEDS-C Baseline Assessment

PDC 10
Rev 0
12/17/2004
Page 2 of 5

Please Use Black Pen To Fill Out Form.

14791

Week # week	Date of Assessment assessdft	Patient ID idn	Patient Letter Code letcode	corrfix Correction
mm	/ dd / yyyy	- - -	- - -	

Anthropometry (Continued)

CRA Use
Only

10.A. Has a DXA scan been performed?

Yes No **bldxa**

B. If **Yes**, date of scan:

bldxadtt / mm / dd / yyyy

11.A. Has a Bio-electrical Impedance Analysis been performed?

Yes No **blbia**

B. If **Yes**, date of BIA:

blbiadt / mm / dd / yyyy

12.A. Has the parent / patient been given the 3-day food diary and been instructed?

Yes No **bldry**

B. If **Yes**, date of first diary day:

bldrydt / mm / dd / yyyy

13.A. Has the Physical Activity Assessment been completed?

Yes No **blpact**

B. If **Yes**, date completed:

blpactdt / mm / dd / yyyy

Concurrent Medication and Conditions

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

Yes No **blpatrb**

If **No**, skip to item 15.

B. Was a Concurrent Medical Conditions form completed?

Yes No **blcncn**

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

blcncndt / mm / dd / yyyy

C. Was a Serious Adverse Event form completed?

Yes No **blsae**

1. If **Yes**, date of SAE form:

blsaedt / mm / dd / yyyy

D. Was an Adverse Event form completed?

Yes No **blae**

1. If **Yes**, date of AE form:

blaedt / mm / dd / yyyy

Signature: _____

Certif. #: _____

staffid2 - - -

PEDS-C Baseline Assessment

PDC 10
Rev 0
12/17/2004
Page 3 of 5

Please Use Black Pen To Fill Out Form.

42909

Week #

Date of Assessment

Patient ID

Patient
Letter Code

week

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assessdt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

idn

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letcode

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Corrfix
Correction

Concurrent Medication and Conditions

CRA Use
Only

15.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 **blnwmd**

If **No**, skip to item 16.

B. Was a Concurrent Medications form completed?

Yes No **blcnmd**

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

blcnmdt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

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

If **No**, skip to item 17.

Yes No **blfem**

B. Has a urine pregnancy test been done?

Yes No **blurn**

1. If **Yes**, urine pregnancy test result:

Positive Negative **blurnres**

2. If **Yes**, date of the test:

blurndt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

If the urine test was **Negative**, skip to item 18.

3. Serum pregnancy test result:

Positive Negative **blsrmsres**

4. Date of the serum test:

blsrmdt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

If the urine or serum test was **Positive**, DO NOT BEGIN DRUG THERAPY and withdraw the patient from the study (no further visits).

5. Date of Withdrawal / Close-out form:

blwdpgdt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

Skip to item 21.

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

Yes No **blmal**

If **No**, skip to item 18.

B. If **Yes**, is his sexual partner pregnant?

Yes No **blmalprg**

If **No**, skip to item 18. If **Yes**, DO NOT BEGIN DRUG THERAPY and withdraw the patient from the study

C. Date of Withdrawal / Close-out form:

blwdmldt

<small>mm</small>		<small>dd</small>		<small>yyyy</small>	

Signature: _____

Certif. #: _____

staffid3

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PEDS-C Baseline Assessment

PDC 10
Rev 0
12/17/2004
Page 5 of 5

Please Use Black Pen To Fill Out Form.

979

Week # week	Date of Assessment assessdt	Patient ID idn	Patient Letter Code letcode	Corrfix Correction
mm	/ dd /	yyyy		

Quality of Life Tests Administered at Baseline

Test Name	1. Completed		2. Form date			3. Completed by		CRA Use Only
	Yes	No	mm	dd	yyyy	Patient	Parent	
23.A. CHQ (Patient)	blchqpt <input type="radio"/>	<input type="radio"/>	blchqptdt	/	/		blchqptby	
B. CHQ (Parent)	blchqpr <input type="radio"/>	<input type="radio"/>	blchqprdt	/	/		blchqprby	
C. BRIEF (Parent)	blbrief <input type="radio"/>	<input type="radio"/>	blbriefdt	/	/		blbriefby <input type="radio"/>	
D. CBCL (Parent)	blcbcl <input type="radio"/>	<input type="radio"/>	blcbcldt	/	/		blcbclby <input type="radio"/>	
E. ABCL (Parent)	blabcl <input type="radio"/>	<input type="radio"/>	blabcldt	/	/		blabclby <input type="radio"/>	
F. LEC (Patient)	bllec <input type="radio"/>	<input type="radio"/>	bllecdt	/	/		bllecby <input type="radio"/>	
G. SF-36 (Parent)	blsf36 <input type="radio"/>	<input type="radio"/>	blsf36dt	/	/		blsf36by <input type="radio"/>	

Signature: _____

Certif. #: **staffid5** -