PEDS-C
Screening Visit 1 Form

37000

Please Use Black Pen To Fill Out Form.

Week # ___ **Date of Assessment** __ / __ / ____ (mm / dd / yyyy) **Patient ID** __ - ___ - _ **Patient Letter Code** ___ ○ **Correction**

Instructions

Before starting this exam, call the DCC to register the patient and to get a patient ID and lettercode. All screening assessments are to be obtained 1 to 35 days before the Baseline visit. The liver biopsy must be performed within 24 months of the screening visit.

Demographics

CRA Use Only

1. Patient's birth date: __ / __ / ____ (mm / dd / yyyy)
2. Patient's gender: Male ○ Female ○

3.A. Patient's ethnic identification: Hispanic or Latino ○ Not Hispanic or Latino ○ Unknown ○

B. Patient's racial identification (Answer each item):

	Yes	No		Yes	No
1. American Indian or Alaskan Native	○	○	4. Native Hawaiian or Pacific Islander	○	○
2. Asian	○	○	5. White	○	○
3. Black or African American	○	○	6. Unknown	○	○

Vital Signs and Physical Measurements

4. Weight: ___ . _ kg
5. Height: ___ . _ cm

6.A. Temperature: __ . _ C

6.B. Site: Oral ○ Tympanic ○ Axillary ○ Unable to Obtain ○

7.Blood Pressure: A. Systolic ___ mmHg B. Diastolic ___ mmHg Unable to obtain ○

8. Pulse: ___ bpm Unable to obtain ○

Informed Consent

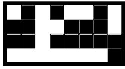
	Yes	No	NA
9. Has informed consent been obtained from a parent / guardian?	○	○	
10. Has assent been obtained from the patient?	○	○	○

Medical History

11. Indicate PAST medical conditions (excluding the illness being treated in the study) by indicating if the appropriate organ system or condition is within normal limits. Complete the rest of the item, if response is **No.**

	1. **Yes**	**No**	2. **Specify / Comment**	3. Still a problem? **Yes**	**No**
A. Ear, Nose, throat:	○	○		○	○
B. Eyes:	○	○		○	○

Signature: ______________________ **Certif. #:** __ - ___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Screening Visit 1 Form

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Week # | **Date of Assessment** ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy) | **Patient ID** ___ ___ - ___ ___ ___ - ___ | **Patient Letter Code** ___ ___ ___ | ○ **Correction**

CRA Use Only

Medical History (Continued)

11. Indicate PAST medical conditions (excluding the illness being treated in the study) by indicating if the appropriate organ system or condition is within normal limits. Complete the rest of the item, if response is **No**.

	1. **Yes**	**No**	2. **Specify / Comment**	3. Still a problem? **Yes**	**No**
C. Respiratory:	○	○		○	○
D. Cardiovascular:	○	○		○	○
E. Gastrointestinal:	○	○		○	○
F. Hepatobiliary or Pancreas:	○	○		○	○
G. Urinary system:	○	○		○	○
H. Reproductive system:	○	○		○	○
I. Neurologic:	○	○		○	○
J. Blood and Lymphatic:	○	○		○	○
K. Endocrine and Metabolic:	○	○		○	○
L. Musculoskeletal:	○	○		○	○
M. Skin:	○	○		○	○
N. Psychiatric:	○	○		○	○
O. Drug allergies:	○	○		○	○
P. Food allergies:	○	○		○	○
Q. Environmental allergies:	○	○		○	○
R. Active substance abuse:	○	○		○	○
S. Other:	○	○		○	○

12. Date of initial HCV diagnosis: ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy) **Date Unknown** ○

Signature: ____________________ **Certif. #:** ___ ___ - ___ ___ ___

Week # | **Date of Assessment** ___ / ___ / ___ (mm / dd / yyyy) | **Patient ID** ___ - ___ - ___ | **Patient Letter Code** | ○ **Correction**

Medical History (Continued)

CRA Use Only

13. Probable route of HCV transmission (Choose one):

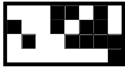
○ **Vertical/Perinatal** ○ **Transfusion recipient**
○ **Sexual contact** ○ **Unknown**
○ **IV Drug use** ○ **Other** **Specify:**

14. List the patient's CURRENT medications:

A. Drug 1:
1. Name:
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: ___ / ___ / ___ (mm / dd / yyyy) **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: 6. Dose unit:
7. Frequency:
8. Indication: ______

B. Drug 2:
1. Name:
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: ___ / ___ / ___ (mm / dd / yyyy) **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: 6. Dose unit:
7. Frequency:
8. Indication: ______

Signature: ______ **Certif. #:** ___ - ___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Week # | **Date of Assessment** (mm / dd / yyyy) | **Patient ID** (- -) | **Patient Letter Code** | ○ **Correction**

Medical History (Continued)

CRA Use Only

14. List the patient's CURRENT medications:

C. Drug 3:
1. Name:
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: mm / dd / yyyy **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: 6. Dose unit:
7. Frequency:
8. Indication: ______

D. Drug 4:
1. Name:
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: mm / dd / yyyy **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: 6. Dose unit:
7. Frequency:
8. Indication: ______

E. Drug 5:
1. Name:
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: mm / dd / yyyy **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: 6. Dose unit:
7. Frequency:
8. Indication: ______

Signature: ______ **Certif. #:** -

Please Use Black Pen To Fill Out Form.

Week # ☐☐☐ **Date of Assessment** ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy) **Patient ID** ☐☐ - ☐☐☐ - ☐ **Patient Letter Code** ☐☐☐ ○ **Correction**

CRA Use Only

Medical History (Continued)

14. List the patient's CURRENT medications:

F. Drug 6:
1. Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy) **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: ☐☐☐☐ 6. Dose unit: ☐☐☐☐☐☐
7. Frequency: ☐☐☐☐☐☐☐☐☐☐
8. Indication: ______________________

G. Drug 7:
1. Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
2. Source: ○ **Brand** ○ **Generic** ○ **Unknown**
3. Date started: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy) **Date Unknown** ○
4. Route of administration: ○ **PO** ○ **PR** ○ **SC** ○ **IM** ○ **IV** ○ **Other**
5. Dose: ☐☐☐☐ 6. Dose unit: ☐☐☐☐☐☐
7. Frequency: ☐☐☐☐☐☐☐☐☐☐
8. Indication: ______________________

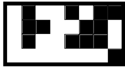
	Yes	**No**
15. Has the patient demonstrated that he/she is able to swallow a RV / placebo tablet?	○	○
16. Is the patient a sexually active female at least 10 years old or a sexually active male?	○	○

If **No**, skip to item 19.

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

	Yes	**No**
A. Oral contraceptive	○	○
B. Intrauterine contraceptive device	○	○
C. Depot contraceptives (implants, injectables)	○	○
D. Physical barrier (condom, diaphragm)	○	○
E. Abstinence	○	○

Signature: ______________________ **Certif. #:** ☐☐ - ☐☐☐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Week #	Date of Assessment (mm / dd / yyyy)	Patient ID	Patient Letter Code	Correction
	/ /	- -		○

CRA Use Only

Medical History (Continued)

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

	Yes	No
F. None	○	○
G. Other	○	○

Specify ______________________________

18. If the patient is a sexually active male, is his current partner pregnant?

Yes	No	Unknown
○	○	○

Physical Exam

19. 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:	○	○	
B. Nose, mouth, throat:	○	○	
C. Neck:	○	○	
D. Chest (including breasts, axillae):	○	○	
E. Genitalia, groin, buttocks:	○	○	
F. Abdomen:	○	○	
G. Each extremity:	○	○	
H. Back, including spine:	○	○	
I. Skin:	○	○	

Signature: ______________________________ **Certif. #:** [ ][ ] - [ ][ ][ ]

Week #	Date of Assessment	Patient ID	Patient Letter Code	
	mm / dd / yyyy	- -		○ Correction

Physical Exam (Continued)

CRA Use Only

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

	1. **Yes**	**No**	2. **Specify**
A. Neurologic:	○	○	
B. Psychologic:	○	○	
C. Genitourinary:	○	○	
D. Hematologic / Lymphatic:	○	○	
E. Allergies / Immunologic:	○	○	
F. Musculoskeletal:	○	○	
G. Other:	○	○	

21. List of laboratory tests ordered at Screening Visit 1.

	Done	**Unable to obtain**		**Done**	**Unable to obtain**
A. Immunology:	○	○	F. Thyroid function:	○	○
B. Hematology:	○	○	G. HCV genotyping:	○	○
C. PT/PTT:	○	○	H. Serum bank:	○	○
D. Chemistry / Pregnancy:	○	○	I. Urinalysis:	○	○
E. HCV - RNA:	○	○			

Depression Screen

22. Was the patient's score on the CDI greater than 19? **Yes** ○ **No** ○

If **No**, skip to item 25.

23. Indicate depressive symptoms present nearly every day during the same two week period which represent a change from the previous level of functioning (Answer each item below).

	Yes	**No**
A. Depressed mood most of the day	○	○
B. Markedly diminished interest or pleasure in all or almost all activities.	○	○
C. Clinically significant weight loss in the absence of dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or a decrease in appetite, including failure to make expected growth-related weight gains.	○	○
D. Insomnia or hypersomnia	○	○

Signature: ____________________ **Certif. #:** [ ][ ] - [ ][ ][ ]

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	/ /	- -		○

CRA Use Only

Depression Screen (Continued)

	Yes	No
23.E. Observable psychomotor agitation or retardation	○	○
F. Fatigue or loss of energy	○	○
G. Feelings of worthlessness or excessive or inappropriate guilt	○	○
H. Diminished ability to think or concentrate or indecisiveness	○	○
I. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide	○	○
24. Are **five** of the above symptoms of a major depressive episode present?	○	○

If **Yes**, DO NOT ENROLL THE PATIENT and skip to signature and Certification #.

Ophthalmologic Exam

	Yes	No
25.A. Has the patient had an ophthalmology exam?	○	○

If **No**, skip to item 26.

B. Date of Ophthalmology Summary: ___ / ___ / ____ (mm / dd / yyyy)

	Yes	No
C. Did the patient have severe retinopathy?	○	○

Liver Biopsy

	Yes	No
26.A. Has the patient had a liver biopsy in the last 24 months?	○	○

If **No**, skip to signature and Certification #.

B. Date of liver biopsy: ___ / ___ / ____ (mm / dd / yyyy)

Signature: ______________________ **Certif. #:** ___ - ___