Follow-Up Evaluation (Pediatric)

Patient ID __ __ - __ **ID** __ - __ __ __
Date of Evaluation: **DOEDATE**
Protocol timepoint *(see codes)*: **TMPT**

Date of last (routine) protocol evaluation visit *(mm/dd/yy)*: **LVM** / **LVD** / **LVY**

SECTION I: MEDICAL HISTORY

1. Do you have or are you being treated for:

	Yes	No	Unknown	
a. Diabetes	☐	☐	☐	**MXDIAB**
b. Anemia	☐	☐	☐	**MXANEM**
c. Neutropenia	☐	☐	☐	**MXNEUT**
d. Thrombocytopenia	☐	☐	☐	**MXTHROM**
e. Coagulation abnormality	☐	☐	☐	**MXCOAG**
f. Other cytopenia	☐	☐	☐	**MXCYTP**
specify_____				**MXCYTPS**
g. Infections				
i. HCV	☐	☐	☐	**MXHCV**
ii. HDV	☐	☐	☐	**MXHDV**
h. Other liver disease				
i. Non-alcoholic fatty liver disease	☐	☐	☐	**MXNASH**
ii. Autoimmune	☐	☐	☐	**MXAUTO**
iii. Genetic/metabolic	☐	☐	☐	**MXMETAB**
i. Glomerulonephritis	☐	☐	☐	**MXGN**
j. Malignancy (other than HCC)	☐	☐	☐	**MXMAL**
specify _____ **MXMALS** _____				

SECTION II: MEDICATIONS

1. Is the patient currently taking medication for any of the following reasons? ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)* **MEDHX**

☐ Immunosuppressants **MEDIMM** ☐ Bronchodilators **MEDBRON** ☐ Antihistamines **MEDHIST**
☐ Anticonvulsants **MEDSEIZ** ☐ Anti-diabetic agents **MEDDIAB** ☐ Estrogen/birth control pills **MEDEST**
☐ Analgesic/pain medications **MEDPAIN** ☐ Antifungals **MEDFUNG** ☐ Acne **MEDACNE**
☐ ADHD **MEDADHD** ☐ Antidepressant/Anxiolytic/Antipsychotic **MEDPSY**
☐ Other antivirals (e.g. famciclovir) **MEDOTH**

2. Is the patient currently taking any herbs, “natural” or herbal medications? ☐ Yes ☐ No ☐ Unknown **MEDHERB**
3. Is the patient currently taking vitamins or minerals? ☐ Yes ☐ No ☐ Unknown **MEDVIT**
   If Yes, *(check all that apply)*

☐ Multi-vitamin **VITMULT** ☐ Vitamin D **VITD** ☐ Vitamin E **VITE** ☐ Folate **VITFOL** ☐ Iron **VITFE** ☐ Calcium **VITCA** ☐ Other **VITOTH**

SECTION III: SYMPTOMS ☐ Check if section not completed NOSYMP

During the last month, how much has the patient been bothered by the following:

		None at all	A little bit	Moderately	Quite a bit	Extremely
Fatigue	SAFAT	☐	☐	☐	☐	☐
Pain over liver	SAPLIV	☐	☐	☐	☐	☐
Nausea	SANAU	☐	☐	☐	☐	☐
Poor appetite	SAAPP	☐	☐	☐	☐	☐
Weight loss	SAWGT	☐	☐	☐	☐	☐
Itching	SAITCH	☐	☐	☐	☐	☐
Irritability	SAIRR	☐	☐	☐	☐	☐
Depression/sadness	SADEPR	☐	☐	☐	☐	☐
Jaundice	SAJAU	☐	☐	☐	☐	☐
Dark urine	SAURN	☐	☐	☐	☐	☐

SECTION IV: PHYSICAL EXAM

					Not done
1. Height	_HGT_	1 ☐ inches	2 ☐ cm	HINCM	☐
2. Weight	_WGT_	1 ☐ lbs.	2 ☐ kg	WLBKG	☐
3. Waist	_WAIST_	1 ☐ inches	2 ☐ cm	WINCM	☐
4. Blood pressure	__ BPS __ / __ BPD __ mmHg				☐

5. Does the patient currently have any of the following conditions:
   a. Jaundice ☐ Yes ☐ No ☐ Not done PEJAU
   b. Tender liver ☐ Yes ☐ No ☐ Not done PETL
   c. Enlarged liver ☐ Yes ☐ No ☐ Not done PEEN
   d. Enlarged spleen ☐ Yes ☐ No ☐ Not done PESP
   e. Peripheral edema ☐ Yes ☐ No ☐ Not done PEEDMA
   f. Muscle wasting ☐ Yes ☐ No ☐ Not done PEMW
   g. Spider angiomata ☐ Yes ☐ No ☐ Not done PESA
   h. Palmar erythema ☐ Yes ☐ No ☐ Not done PEPALM
6. Date of menarche *(mm/yy)*: MENM / MENY ☐ N/A
7. Is the patient pregnant? ☐ Yes ☐ No ☐ N/A PREG
   If Yes, Date of last menstrual period *(mm/dd/yy)*: LMENM / LMEND / LMENY

SECTION V: LIVER DECOMPENSATION OR HCC

1. Does the patient currently have:

	Yes	No	Unknown			
a. Cirrhosis	☐	☐	☐	HXCIRR		
b. Hepatic encephalopathy	☐	☐	☐	HXENC	If Yes, stage: 1 ☐ mild 2 ☐ moderate-severe	
c. Esophageal/gastric varices	☐	☐	☐	HXVARC		HXENCST
If Yes, variceal bleeding	☐	☐	☐	HXVBLE		
d. Ascites	☐	☐	☐	HXASC	If Yes, grade: 1 ☐ mild 2 ☐ moderate-severe	
e. HCC	☐	☐	☐	HXHCC		HXASCGD

NOTE: If initial diagnosis of cirrhosis, liver decompensation or HCC, complete the Follow-Up Events Form

SECTION VI: DIAGNOSTIC TESTS

1. Imaging performed, since the last protocol visit? ☐ Yes ☐ No **IMG**
   If Yes,
   a. Date of most recent test *(mm/yy)*: **IMGM** / **IMGY**
   b. Tests performed *(check all that apply)*:
   ☐ CT ☐ MRI ☐ Liver ultrasound ☐ PET ☐ PET/CT ☐ Other ___ **IMOS** ___
   IMCT **IMMRI** **IMULT** **IMPET** **IMPETCT** **IMO**
   c. Report(s) available? ☐ Yes ☐ No **IMREP**
   If Yes, results:

i. Nodular liver	☐ Yes	☐ No	☐ Unknown	**IMNOD**
ii. Abnormal liver texture	☐ Yes	☐ No	☐ Unknown	**IMABT**
iii. Enlarged spleen	☐ Yes	☐ No	☐ Unknown	**IMSPN**
iv. Ascites	☐ Yes	☐ No	☐ Unknown	**IMASC**
v. Venous collaterals	☐ Yes	☐ No	☐ Unknown	**IMVEN**
vi. Changes indicative of steatosis	☐ Yes	☐ No	☐ Unknown	**IMSTEAT**
vii. Other _____ **IMOTHS** _____	☐ Yes	☐ No	☐ Unknown	**IMOTH**

2. Liver biopsy, since the last protocol visit? ☐ Yes ☐ No **LBX**
   If Yes,
   a. Date of most recent biopsy *(mm/dd/yy)*: **LBXM** / **LBXD** / **LBXY**
   b. Slides requested? ☐ Yes ☐ No **LBXSL**

NOTE: Complete the Liver Biopsy and Special Visit forms for every biopsy performed.

SECTION VII: TREATMENT

1. Has patient received treatment for HBV since the last protocol visit? ☐ Yes ☐ No ☐ Unknown **TXHBV**
   If Yes, record all treatments received during the interval:

Antiviral Therapy (see codes)	Date Started* *(mm/dd/yyyy)*	Date Stopped* *(mm/dd/yyyy)*	**or** Currently on Therapy
TXB1	**TXB1BM/D/Y**	**TXB1EM/D/Y**	**TXB1CUR**
TXB2	**TXB2BM/D/Y**	**TXB2EM/D/Y**	**TXB2CUR**
TXB3	**TXB3BM/D/Y**	**TXB3EM/D/Y**	**TXB3CUR**
TXB4	**TXB4BM/D/Y**	**TXB4EM/D/Y**	**TXB4CUR**
TXB5	**TXB5BM/D/Y**	**TXB5EM/D/Y**	**TXB5CUR**
TXB6	**TXB6BM/D/Y**	**TXB6EM/D/Y**	**TXB6CUR**

1 = IFN
2 = Entecavir
3 = Telbivudine
4 = Lamivudine
5 = Adefovir
6 = Peg-IFN
7 = Tenofovir
8 = Emtricitabine
9 = Truvada
10 = HBV masked trial
15= Accupunture
16= Scarification
17=Coining
-3= Unknown

* record UNK for any piece of the date that is not known

SECTION VIII: SEROLOGIES

Instructions: *Record the result for each. If a lab was not completed at the time of the evaluation, check "Not done".*

Date of sample *(mm/dd/yy)*: **SSAMPM/SSAMPD/SSAMPY**

		Positive	Negative	Equivocal	Date of Sample *(If different from above) mm/dd/yy*	Not done
1. HBsAg	**HBSAG**	☐	☐	☐	**HBSAGM/HBSAGD/HBSAGY**	☐
2. HBeAg	**HBEAG**	☐	☐	☐	**HBEAGM/HBEAGD/HBEAGY**	☐
3. Anti-HBs	**HBS**	☐	☐	☐	**HBSM/HBSD/HBSY**	☐
4. Anti-HBe	**HBE**	☐	☐	☐	**HBEM/HBED/HBEY**	☐
5. Anti-HDV	**HDV**	☐	☐	☐	**HDVM/HDVD/HDVY**	☐
6. Anti-HCV	**HCV**	☐	☐	☐	**HCVM/HCVD/HCVY**	☐
7. Anti-HIV	**HIV**	☐	☐	☐	**HIVM/HIVD/HIVY**	☐
8. Anti-HBc IgM	**HBC**	☐	☐	☐	**HBCM/HBCD/HBCY**	☐
9. Anti-HAV	**HAVAB**	☐	☐	☐	**HAVABM/HAVABD/HAVABY**	☐

SECTION IX: VIROLOGY TESTS

1. Most recent HBV DNA level: __ **BDNA** __ ☐ Unknown Date *(mm/yy)*: **BDNAM** / **BDNAY**
   Method/Unit: **BUNIT** 1 ☐ IU/mL 2 ☐ copies/mL Lower limit of detection: _ **BDNALL** _

SECTION X: LABS

Instructions: *Record the most recent result for each. If a lab was not completed at the time of the evaluation or within 1 month of the evaluation, check "Not done".*

Date of sample *(mm/dd/yy)*: **LSAMPM/LSAMPD/LSAMPY**

			Date of sample *(If different from above) mm/dd/yy*	Not Done
1. White blood cells	**WBC**	$x10^3/mm^3$	**WBCM/D/Y**	☐
2. Platelets	**PLAT**	$x10^3/mm^3$	**PLATM/D/Y**	☐
3. Hemoglobin	**HGB**	g/dL	**HGBM/D/Y**	☐
4. Hematocrit	**HTC**	%	**HTCM/D/Y**	☐
5. GGT	**GGT**	IU/L	**GGTM/D/Y**	☐
6. ALT	**ALT**	IU/L	**ALTM/D/Y**	☐ ALT normal range: **ALTL** - **ALTU**
7. AST	**AST**	IU/L	**ASTM/D/Y**	☐ AST normal range: **ASTL** - **ASTU**
8. Alkaline phosphatase	**ALKP**	IU/L	**ALKPM/D/Y**	☐ Alk P normal range: **ALKPL** - **ALKPU**
9. Total bilirubin	**TBILI**	mg/dL	**TBILIM/D/Y**	☐
10. Direct bilirubin	**DBILI**	mg/dL	**DBILIM/D/Y**	☐
11. Indirect bilirubin	**IBILI**	mg/dL	**IBILIM/D/Y**	☐
12. Albumin	**ALB**	g/dL	**ALBM/D/Y**	☐
13. Total protein	**TP**	g/dL	**TPM/D/Y**	☐
14. Creatinine	**CREAT**	mg/dL	**CREATM/D/Y**	☐
15. Alpha-fetoprotein	**AFP**	ng/mL	**AFPM/D/Y**	☐
16. INR	**INR**		**INRM/D/Y**	☐

SECTION XI: BIOSPECIMENS

1. Were samples obtained? ☐ Yes ☐ No **BIOSPEC**

   If Yes, *(check all that apply):* ☐ NIDDK repository **NIDDKR** ☐ Genetics **GEN** ☐ Immunology study **IMM** ☐ Central testing lab **CLAB**

SECTION XII: TANNER STAGE

Instructions: *Transcribe responses from the Tanner Stage questionnaire to the items below. If the patient is not of age to complete the Tanner Stage questionnaire, check "Not done".*

1. Physical growth: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV 5 ☐ V ☐ Unknown ☐ Prefer not to answer ☐ Not done
   TANPHY
2. Pubic hair growth: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV 5 ☐ V ☐ Unknown ☐ Prefer not to answer ☐ Not done
   TANPUB

NOTE: If during the follow-up interval the patient died, received a liver transplant, or was diagnosed (for the first time) with hepatic decompensation, HCC, cirrhosis, or was lost to follow-up, complete the Follow-up Event form and other event specific forms as necessary.

Data collector initials: __ **DCID** __

Date data collection completed *(mm/dd/yy)*: **DCM**/**DCD**/**DCY**