Follow-Up Evaluation (Adult)

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. Hypertension	☐	☐	☐	**MXHYPT**
c. Hyperlipidemia	☐	☐	☐	**MXCHOL**
d. Infections				
i. HCV	☐	☐	☐	**MXHCV**
ii. HIV	☐	☐	☐	**MXHIV**
iii. HDV	☐	☐	☐	**MXHDV**
e. Other liver disease				
i. Alcoholic	☐	☐	☐	**MXALC**
ii. Non-alcoholic fatty liver disease	☐	☐	☐	**MXNASH**
iii. Autoimmune	☐	☐	☐	**MXAUTO**
iv. Genetic/metabolic	☐	☐	☐	**MXMETAB**
f. Liver transplant	☐	☐	☐	**MXLIVTX**
g. Glomerulonephritis	☐	☐	☐	**MXGN**
h. Vasculitis / Polyarteritis Nodosa	☐	☐	☐	**MXVASC**
i. 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 **MEDHX**
   If Yes, *(check all that apply)*
   ☐ Immunosuppressants **MEDIMM** ☐ Lipid-lowering agents **MEDLIP** ☐ Anticoagulants **MEDCOAG**
   ☐ Anti-hypertensive agents **MEDHYP** ☐ Anti-diabetic agents **MEDDIAB** ☐ Estrogen/birth control pills **MEDEST**
   ☐ Other antivirals (e.g. famciclovir) **MEDOTH**
2. Is the patient currently taking any herbs, "natural" or herbal medications? ☐ Yes ☐ No **MEDHERB**
3. Is the patient currently taking vitamins or minerals? ☐ Yes ☐ No **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: PHYSICAL EXAM

1. Height: **_HGT_** 1 ☐ inches 2 ☐ cm **HINCM** ☐ Not done
2. Weight: **_WGT_** 1 ☐ lbs. 2 ☐ kg **WLBKG** ☐ Not done
3. Waist: **_WAIST_** 1 ☐ inches 2 ☐ cm **WINCM** ☐ Not done
4. Blood pressure **BPS**__ __ / **BPD**__ __ mmHg ☐ Not done
5. Does the patient currently have any of the following conditions:

a. Jaundice **PEJAU**	☐ Yes	☐ No	☐ Not done	e. Peripheral edema **PEEDMA**	☐ Yes	☐ No	☐ Not done
b. Tender liver **PETL**	☐ Yes	☐ No	☐ Not done	f. Muscle wasting **PEMW**	☐ Yes	☐ No	☐ Not done
c. Enlarged liver **PEEN**	☐ Yes	☐ No	☐ Not done	g. Spider angiomata **PESA**	☐ Yes	☐ No	☐ Not done
d. Enlarged spleen **PESP**	☐ Yes	☐ No	☐ Not done	h. Palmar erythema **PEPALM**	☐ Yes	☐ No	☐ Not done

6. Is patient pregnant now (or during the follow-up interval) or within 72 weeks post-delivery *(check all that apply)*?
   ☐ Yes, pregnant now (or during the follow-up interval): **PREGC** ☐ Yes, w/in 72 weeks **PREG72** ☐ No **PREGNO** ☐ N/A **PREGNA**
   If Yes, pregnant now (or during the follow-up interval):
   Date of last menstrual period prior to pregnancy *(mm/dd/yy)*: **LMENSM** / **LMENSD** / **LMENSY**
   If Yes, w/in 72 weeks post-delivery:Was a pregnancy follow-up form completed at this visit?☐ Yes ☐ No **PFUP**

SECTION IV: LIVER DECOMPENSATION OR HCC

1. Does the patient currently have:

	Yes	No	Unknown	
a. Cirrhosis	☐	☐	☐	**HXCIRR**
b. Hepatic encephalopathy	☐	☐	☐	**HXENC** If Yes, stage:1 ☐ mild2 ☐ moderate-severe
c. Esophageal/gastric varices	☐	☐	☐	**HXVARC** **HXENCST**
If Yes, variceal bleeding	☐	☐	☐	**HXVBLE**
d. Ascites	☐	☐	☐	**HXASC** If Yes, grade:1 ☐ mild2 ☐ moderate-severe
e. HCC	☐	☐	☐	**HXHCC** **HXASCGD**

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

SECTION V: 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 _____ ☐ Yes ☐ No ☐ Unknown **IMOTH / IMOTHS**

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 VI: TREATMENT

1. Has patient received treatment for HBV (interferon, oral agent) since the last protocol visit?

   ☐ Yes ☐ No ☐ N/A, participating in HBV/HIV Co-infected Ancillary Study **(All HBV and HIV therapy should be captured on the AH Log for HBV/HIV co-infected participants.)**

   If Yes, record all antivirals received during the interval: **TXHBV**

Antiviral Therapy (see codes)	Date Started* *(mm/dd/yy)*	Date Stopped* *(mm/dd/yy)*	**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/TDF, 8 = Emtricitabine, 9 = Truvada, 12 = Tenofovir/TAF

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

SECTION VII: SEROLOGIES

Instructions: *Record the result for each. If a lab was not completed at the time of the evaluation or since the previous 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**	☐

SECTION VIII: 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 IX: 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".*
Fasting labs should be performed at annual visits: optimal is 12 hours, minimum of 8 hours

1. Was the patient fasting for this visit? ☐ Yes ☐ No **FASTYN**
   If Yes, number of hours fasting *(round to nearest hour)*: __ __ **FASTHR**

Date of sample *(mm/dd/yy)*: **LSAMPM/D/Y**

			Date of sample (If different from above) *mm/dd/yy*	Not Done	
a. White blood cells	**WBC**	x10^3/mm^3	**WBCM/D/Y**	☐	
b. Platelets	**PLAT**	x10^3/mm^3	**PLATM/D/Y**	☐	
c. Hemoglobin	**HGB**	g/dL	**HGBM/D/Y**	☐	
d. Hematocrit	**HTC**	%	**HTCM/D/Y**	☐	
e. ALT	**ALT**	IU/L	**ALTM/D/Y**	☐	ALT normal range: **ALTL** - **ALTU**
f. AST	**AST**	IU/L	**ASTM/D/Y**	☐	AST normal range: **ASTL** - **ASTU**
g. Alkaline phosphatase	**ALKP**	IU/L	**ALKPM/D/Y**	☐	Alk P normal range: **ALKPL** - **ALKPU**
h. Total bilirubin	**TBILI**	mg/dL	**TBILIM/D/Y**	☐	
i. Direct bilirubin	**DBILI**	mg/dL	**DBILIM/D/Y**	☐	
j. Indirect bilirubin	**IBILI**	mg/dL	**IBILIM/D/Y**	☐	
k. Albumin	**ALB**	g/dL	**ALBM/D/Y**	☐	
l. Total protein	**TP**	g/dL	**TPM/D/Y**	☐	
m. Creatinine	**CREAT**	mg/dL	**CREATM/D/Y**	☐	
n. Alpha-fetoprotein	**AFP**	ng/mL	**AFPM/D/Y**	☐	
o. INR	**INR**		**INRM/D/Y**	☐	

SECTION IX: LABS (Continued)

				Date of sample (If different from above) *mm/dd/yy*	Not Done
p.	Cholesterol (total)	TCHOL	mg/dL	TCHOLM/D/Y	☐
q.	Triglycerides	TGY	mg/dL	TGYM/D/Y	☐
r.	HDL	HDL	mg/dL	HDLM/D/Y	☐
s.	LDL	LDL	mg/dL	LDLM/D/Y	☐
t.	Glucose	GLU	mg/dL	GLUM/D/Y	☐
u.	Insulin	INS	mcU/mL	INSM/D/Y	☐

SECTION X: FIBROSCAN and BREATH TEST

1. Was fibroscan performed as part of evaluation: ☐ Yes ☐ No FBS
   If Yes, date of fibroscan *(mm/dd/yy)*: FBSM/FBSD/FBSY *(Complete the Fibroscan form)*
2. Was breath test performed as part of evaluation: ☐ Yes ☐ No BT
   If Yes, date of breath test *(mm/dd/yy)*: BTM/BTD/BTY *(Complete the Breath Test form)*

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

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/yyyy)*:DCM/DCD/DCY