Follow-Up Evaluation (Adult)

Patient ID __ __ - __ __ __ __ - __ __ __
Date of Evaluation: ___ / ___ / _____
Protocol timepoint *(see codes)*: ____

Date of last (routine) protocol evaluation visit *(mm/dd/yy)*:
___ / ___ / ___

SECTION I: MEDICAL HISTORY

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

	Yes	No	Unknown
a. Diabetes	☐	☐	☐
b. Hypertension	☐	☐	☐
c. Hyperlipidemia	☐	☐	☐
d. Infections			
i. HCV	☐	☐	☐
ii. HIV	☐	☐	☐
iii. HDV	☐	☐	☐
e. Other liver disease			
i. Alcoholic	☐	☐	☐
ii. Non-alcoholic fatty liver disease	☐	☐	☐
iii. Autoimmune	☐	☐	☐
iv. Genetic/metabolic	☐	☐	☐
f. Liver transplant	☐	☐	☐
g. Glomerulonephritis	☐	☐	☐
h. Vasculitis / Polyarteritis Nodosa	☐	☐	☐
i. Malignancy (other than HCC) specify, _____	☐	☐	☐

SECTION II: MEDICATIONS

1. Is the patient currently taking medication for any of the following reasons? ☐ Yes ☐ No
   If Yes, (*check all that apply)*
   ☐ Immunosuppressants ☐ Lipid-lowering agents ☐ Anticoagulants
   ☐ Anti-hypertensive agents ☐ Anti-diabetic agents ☐ Estrogen/birth control pills
   ☐ Other antivirals (e.g. famciclovir)
2. Is the patient currently taking any herbs, “natural” or herbal medications? ☐ Yes ☐ No
3. Is the patient currently taking vitamins or minerals? ☐ Yes ☐ No
   If Yes, *(check all that apply)*
   ☐ Multi-vitamin ☐ Vitamin D ☐ Vitamin E ☐ Folate ☐ Iron ☐ Calcium ☐ Other

SECTION III: PHYSICAL EXAM

1. Height: _____.__ 1 ☐ inches 2 ☐ cm ☐ Not done
2. Weight: _____.__ 1 ☐ lbs. 2 ☐ kg ☐ Not done
3. Waist: _____.__ 1 ☐ inches 2 ☐ cm ☐ Not done
4. Blood pressure __ __ __ / __ __ __ mmHg ☐ Not done
5. Does the patient currently have any of the following conditions:

a. Jaundice	☐ Yes	☐ No	☐ Not done	e. Peripheral edema	☐ Yes	☐ No	☐ Not done
b. Tender liver	☐ Yes	☐ No	☐ Not done	f. Muscle wasting	☐ Yes	☐ No	☐ Not done
c. Enlarged liver	☐ Yes	☐ No	☐ Not done	g. Spider angiomata	☐ Yes	☐ No	☐ Not done
d. Enlarged spleen	☐ Yes	☐ No	☐ Not done	h. Palmar erythema	☐ Yes	☐ No	☐ Not done

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

SECTION IV: LIVER DECOMPENSATION OR HCC

1. Does the patient currently have:

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

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
   If Yes,
   a. Date of most recent test *(mm/yy)*: ___ /_____
   b. Tests performed *(check all that apply)*:
   ☐ CT ☐ MRI ☐ Liver ultrasound ☐ PET ☐ PET/CT ☐ Other _____
   c. Report(s) available? ☐ Yes ☐ No
   If Yes, results:

i. Nodular liver	☐ Yes	☐ No	☐ Unknown
ii. Abnormal liver texture	☐ Yes	☐ No	☐ Unknown
iii. Enlarged spleen	☐ Yes	☐ No	☐ Unknown
iv. Ascites	☐ Yes	☐ No	☐ Unknown
v. Venous collaterals	☐ Yes	☐ No	☐ Unknown
vi. Changes indicative of steatosis	☐ Yes	☐ No	☐ Unknown
vii. Other _____	☐ Yes	☐ No	☐ Unknown

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

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:

Antiviral Therapy (see codes)	Date Started* *(mm/dd/yy)*	Date Stopped* *(mm/dd/yy)*	**or** Currently on Therapy
_____	___ / ___ / ___	___ / ___ / ___	☐
_____	___ / ___ / ___	___ / ___ / ___	☐
_____	___ / ___ / ___	___ / ___ / ___	☐
_____	___ / ___ / ___	___ / ___ / ___	☐
_____	___ / ___ / ___	___ / ___ / ___	☐
_____	___ / ___ / ___	___ / ___ / ___	☐

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)*: ___ / ___ / ____

	Positive	Negative	Equivocal	Date of Sample *(If different from above)* *mm/dd/yy*	Not done
1. HBsAg	☐	☐	☐	___ / ___ / ____	☐
2. HBeAg	☐	☐	☐	___ / ___ / ____	☐
3. Anti-HBs	☐	☐	☐	___ / ___ / ____	☐
4. Anti-HBe	☐	☐	☐	___ / ___ / ____	☐
5. Anti-HDV	☐	☐	☐	___ / ___ / ____	☐
6. Anti-HCV	☐	☐	☐	___ / ___ / ____	☐
7. Anti-HIV	☐	☐	☐	___ / ___ / ____	☐
8. Anti-HBc IgM	☐	☐	☐	___ / ___ / ____	☐

SECTION VIII: VIROLOGY TESTS

1. Most recent HBV DNA level: _____ ☐ Unknown Date *(mm/yy)*: ___/___
   Method/Unit: 1 ☐ IU/mL 2 ☐ copies/mL Lower limit of detection: _____

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
   If Yes, number of hours fasting *(round to nearest hour)*: __ __

Date of sample *(mm/dd/yy)*: ___ / ___ / ____

			Date of sample *(If different from above)* *mm/dd/yy*	Not Done	
a. White blood cells	__ __.__	x10^3/mm^3	___ / ___ / ____	☐	
b. Platelets	__ __ __	x10^3/mm^3	___ / ___ / ____	☐	
c. Hemoglobin	__ __.__	g/dL	___ / ___ / ____	☐	
d. Hematocrit	__ __.__	%	___ / ___ / ____	☐	
e. ALT	__ __ __ __	IU/L	___ / ___ / ____	☐	ALT normal range: _____ - _____
f. AST	__ __ __ __	IU/L	___ / ___ / ____	☐	AST normal range: _____ - _____
g. Alkaline phosphatase	__ __ __	IU/L	___ / ___ / ____	☐	Alk P normal range: _____ - _____
h. Total bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
i. Direct bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
j. Indirect bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
k. Albumin	__.__	g/dL	___ / ___ / ____	☐	
l. Total protein	__ __.__	g/dL	___ / ___ / ____	☐	
m. Creatinine	__.__	mg/dL	___ / ___ / ____	☐	
n. Alpha-fetoprotein	__ __ __ __.__	ng/mL	___ / ___ / ____	☐	
o. INR	__ __.__		___ / ___ / ____	☐	

SECTION IX: LABS (Continued)

			Date of sample *(If different from above)* *mm/dd/yy*	Not Done
p. Cholesterol (total)	__ __ __	mg/dL	___ / ___ / ____	☐
q. Triglycerides	__ __ __ __	mg/dL	___ / ___ / ____	☐
r. HDL	__ __ __.__	mg/dL	___ / ___ / ____	☐
s. LDL	__ __ __.__	mg/dL	___ / ___ / ____	☐
t. Glucose	__ __ __	mg/dL	___ / ___ / ____	☐
u. Insulin	__ __ __.__	mcU/mL	___ / ___ / ____	☐

SECTION X: FIBROSCAN and BREATH TEST

1. Was fibroscan performed as part of evaluation: ☐ Yes ☐ No
   If Yes, date of fibroscan *(mm/dd/yy)*: ___ / ___ / ____ *(Complete the Fibroscan form)*

2. Was breath test performed as part of evaluation: ☐ Yes ☐ No
   If Yes, date of breath test *(mm/dd/yy)*: ___ / ___ / ____ *(Complete the Breath Test form)*

SECTION XI: BIOSPECIMENS

1. Were samples obtained? ☐ Yes ☐ No

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

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: __ __ __
Date data collection completed *(mm/dd/yyyy)*: ___ / ___ / ___