Baseline Evaluation (Adult)

Patient ID __ __ - __ __ __ __ - __ __ __

Date of Evaluation: ___ / ___ / _____

Screening Log Reference: Page ____ Line____

SECTION I: DEMOGRAPHICS

1. Patient's country of birth: _____ (Code) _____ (Country) *(enter code or country)* ☐ Unknown

   If not born in the United States or Canada, year patient came to U.S. or Canada *(yyyy)*: _____ ☐ Unknown

2. Patient's parents countries of birth:

   a. Birth Mother _____ _____ *(enter code or country)* ☐ Unknown

   b. Birth Father _____ (Code) _____ (Country) *(enter code or country)* ☐ Unknown

3. Highest level of school completed *(check only one)*:

   1 ☐ None or some grade school
   2 ☐ Grade school
   3 ☐ Some high school
   4 ☐ High school diploma or equivalent (GED)
   5 ☐ Some college, no degree
   6 ☐ Vocational or Technical School
   7 ☐ Associate (2 year) degree
   8 ☐ Bachelor's degree
   9 ☐ Master's degree
   10 ☐ Doctoral degree
   11 ☐ Other degree: _____
   ☐ Prefer not to answer

4. Current employment status *(check only one)*:

   1 ☐ Employed at a job for pay, full-time
   2 ☐ Employed at a job for pay, part-time
   3 ☐ Homemaker, not currently working for pay
   4 ☐ Not currently employed, retired
   5 ☐ Not currently employed, not retired
   6 ☐ Other: _____

   If 1 or 2, go to question 4.1
   If 3, 4, or 5, go to question 4.3

   ☐ Prefer not to answer

   4.1 Are you employed outside of the home? ☐ Yes ☐ No

   4.2 Have you had to reduce the number of hours that you work in an average week because of your hepatitis B? ☐ Yes ☐ No

   4.3 Did you stop working because of your hepatitis B? ☐ Yes ☐ No

5. Method of insurance *(check all that apply)*:

   ☐ Medicaid
   ☐ Medicare
   ☐ Tricare
   ☐ Government (not Medicaid/Medicare/Tricare)
   ☐ Private
   ☐ Other, specify _____
   ☐ None / self pay
   ☐ Prefer not to answer

SECTION II: FAMILY HISTORY (BIOLOGICAL FAMILY MEMBERS)

1. Presence of chronic hepatitis B (HBsAg positivity) in family members: ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)*
   ☐ mother ☐ father ☐ siblings ☐ children ☐ spouse/partner ☐ aunts/uncles ☐ grandparents

2. Liver cancer in family members: ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)*
   ☐ mother ☐ father ☐ siblings ☐ children ☐ aunts/uncles ☐ grandparents

3. Diabetes in family members: ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)*
   ☐ mother ☐ father ☐ siblings ☐ children ☐ aunts/uncles ☐ grandparents

SECTION III: 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. HDV	☐	☐	☐
e. Other liver disease			
i. Alcoholic	☐	☐	☐
ii. Non-alcoholic fatty liver disease	☐	☐	☐
iii. Autoimmune	☐	☐	☐
iv. Genetic/metabolic	☐	☐	☐
v. Cirrhosis (if Yes, complete FE form)	☐	☐	☐
f. Glomerulonephritis	☐	☐	☐
g. Vasculitis / Polyarteritis Nodosa	☐	☐	☐
h. Malignancy (other than HCC) specify _____	☐	☐	☐

SECTION IV: MEDICATION HISTORY

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 ☐ Unknown
3. Is the patient currently taking vitamins or minerals? ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)*
   ☐ Multi-vitamin ☐ Vitamin D ☐ Vitamin E ☐ Folate ☐ Iron ☐ Calcium ☐ Other

SECTION V: 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. Has the patient ever been pregnant? ☐ Yes ☐ No ☐ N/A **(If Yes, complete the Pregnancy Questionnaire)**
7. Is the patient pregnant now? ☐ Yes ☐ No ☐ N/A
   If Yes, date of last menstrual period *(mm/dd/yy)*: ___ /___ / _____

SECTION VI: DIAGNOSTIC TESTS

1. Imaging (within 2 years) performed? ☐ Yes ☐ No ☐ Unknown
   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 within the last 2 years? ☐ Yes ☐ No ☐ Unknown
   If Yes,
   a. Date of most recent biopsy *(mm/yy)*: ___ /_____
   b. Slides requested? ☐ Yes ☐ No

SECTION VII: TREATMENT

1. Has patient ever received treatment for HBV (interferon, oral agent)?
   ☐ 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 treatment ever received:

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

1 = IFN	6 = Peg-IFN
2 = Entecavir	7 = Tenofovir/TDF
3 = Telbivudine	8 = Emtricitabine
4 = Lamivudine	9 = Truvada
5 = Adefovir	12=Tenofovir/TAF
	-3= Unknown

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

SECTION VIII: RISK ASSESSMENT

1. When was the patient diagnosed with HBV *(mm/yyyy)*? ___ / ___ ☐ Unknown
2. Has the patient ever had a blood transfusion? ☐ Yes ☐ No ☐ Unknown
   If Yes, date of first transfusion *(mm/yyyy)*: ___ / _____ ☐ Unknown
3. Has the patient ever had renal dialysis? ☐ Yes ☐ No ☐ Unknown
4. Did the patient ever work in a hospital or other health care setting? ☐ Yes ☐ No ☐ Unknown
   If Yes, did a needle stick occur? ☐ Yes ☐ No ☐ Unknown
   If needle stick occurred, was the source patient hepatitis B positive? ☐ Yes ☐ No ☐ Unknown
5. Has the patient ever used injection drugs except as prescribed by a physician? ☐ Yes ☐ No ☐ Unknown
6. Has the patient ever used intra-nasal illicit drugs? ☐ Yes ☐ No ☐ Unknown
7. Has the patient ever lived with someone who had hepatitis B when they were living together or shared household items (i.e. razors, toothbrushes, nail clippers) with someone who had hepatitis B?
   ☐ Yes ☐ No ☐ Unknown
8. Has the patient ever had a body piercing other than the ears? ☐ Yes ☐ No ☐ Unknown
   If Yes, was the piercing done by a professional? ☐ Yes ☐ No ☐ Unknown
9. Has the patient ever had a tattoo? ☐ Yes ☐ No ☐ Unknown
   If Yes, was the tattoo done by a professional? ☐ Yes ☐ No ☐ Unknown
10. Was the patient's birth mother ever diagnosed with hepatitis B? ☐ Yes ☐ No ☐ Unknown

SECTION IX: SEROLOGIES AND AUTOANTIBODIES

Instructions: *Record the most recent result for each. If a test was never performed or a result is not available, check "Not done".*

	Positive	Negative	Equivocal	Titer	Date of sample *(mm/yyyy)*	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	☐	☐	☐		___/____	☐	→ At eval if acute hep B is suspected
9. ANA	☐	☐	☐	1: _____	___/____	☐	
10. ASMA	☐	☐	☐	1: _____	___/____	☐	
11. ALKM	☐	☐	☐	1: _____	___/____	☐	

SECTION X: VIROLOGY TESTS

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

SECTION XI: LABS

Instructions: *Record the most recent result for each. If a lab was not completed as part of the baseline evaluation or within 3 months prior to the initial baseline visit, check "Not done".*

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

			Date of sample *(If different from above) mm/dd/yy*	Not Done	
1. White blood cells	__ __.__	x10^3/mm^3	___ / ___ / ____	☐	
2. Platelets	__ __ __	x10^3/mm^3	___ / ___ / ____	☐	
3. Hemoglobin	__ __.__	g/dL	___ / ___ / ____	☐	
4. Hematocrit	__ __.__	%	___ / ___ / ____	☐	
5. ALT	__ __ __ __	IU/L	___ / ___ / ____	☐	ALT normal range: _____ - _____
6. AST	__ __ __ __	IU/L	___ / ___ / ____	☐	AST normal range: _____ - _____
8. Alkaline phosphatase	__ __ __	IU/L	___ / ___ / ____	☐	Alk P normal range: _____ - _____
8. Total bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
9. Direct bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
10. Indirect bilirubin	__ __.__	mg/dL	___ / ___ / ____	☐	
11. Albumin	__.__	g/dL	___ / ___ / ____	☐	
12. Total protein	__ __.__	g/dL	___ / ___ / ____	☐	
13. Creatinine	__.__	mg/dL	___ / ___ / ____	☐	
14. Alpha-fetoprotein	__ __ __ __.__	ng/mL	___ / ___ / ____	☐	
15. INR	__ __.__		___ / ___ / ____	☐	

NOTE: If serum ALT result is ≥ 300 U/L (male) or ≥ 200 U/L (female) then complete Follow-Up Event form

SECTION XII: LABS *(These should be fasting labs - optimal is 12 hours, minimum of 8 hours fasting)*

Instructions: *The following labs should be performed as part of the baseline evaluation. Record the result for each. If a lab was not completed as part of the baseline evaluation, check "Not done".*

1. Was the patient fasting for this visit *(optimal is 12 hours, minimum is 8 hours)?* ☐ 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. Cholesterol (total)	__ __ __	mg/dL	___ / ___ / ____	☐
b. Triglycerides	__ __ __ __	mg/dL	___ / ___ / ____	☐
c. HDL	__ __ __.__	mg/dL	___ / ___ / ____	☐
d. LDL	__ __ __.__	mg/dL	___ / ___ / ____	☐
e. Glucose	__ __ __	mg/dL	___ / ___ / ____	☐
f. Insulin	__ __ __.__	mcU/mL	___ / ___ / ____	☐

SECTION XIII: FIBROSCAN and BREATH TEST

1. Did patient consent to fibroscan testing? ☐ Yes ☐ No ☐ Not participating
2. Was a fibroscan performed as part of the baseline evaluation? ☐ Yes ☐ No
   If Yes, date of fibroscan *(mm/dd/yy)*: ___ / ___ / ____ *(Complete the Fibroscan form)*
3. Did patient consent to the breath testing? ☐ Yes ☐ No ☐ Not participating
4. Was a breath test performed as part of the baseline evaluation? ☐ Yes ☐ No
   If Yes, date of breath test *(mm/dd/yy)*: ___ / ___ / ____ *(Complete the Breath Test form)*

SECTION XIV: BIOSPECIMENS

1. Indicate the status of consent for each:
   a. Serum/plasma for research/storage 1 ☐ Obtained 2 ☐ Refused 3 ☐ Not attempted at this visit
   b. Liver tissue for research/storage 1 ☐ Obtained 2 ☐ Refused 3 ☐ Not attempted at this visit
   c. Genetic sample 1 ☐ Obtained 2 ☐ Refused 3 ☐ Not attempted at this visit
   d. Immunology study 1 ☐ Obtained 2 ☐ Refused 3 ☐ Not attempted at this visit
2. Samples obtained at this visit (*check all that apply*):
   ☐ NIDDK repository (serum/plasma) ☐ Genetics ☐ Immunology study ☐ Central testing lab ☐ None

Note: if participating in immunology study and a patient presents with acute hepatitis B or ALT flare at the initial baseline visit, collect the sample for the immunology study (50mL) and 10mL whole blood for serum at the visit.

SECTION XV: ADMINISTRATIVE

1. Was the baseline evaluation completed in one visit? ☐ Yes ☐ No
   If No, date all components of baseline evaluation were complete (last visit date) *(mm/dd/yy)*: ___ / ___ / ____

2. Does the patient speak English? ☐ Yes ☐ No
   If No, indicate language used to obtain information for HBRN network:
   1 ☐ Spanish 2 ☐ Chinese 3 ☐ Korean 4 ☐ Vietnamese 5 ☐ Other, specify _____

Data collector initials:__ __ __
Date data collection completed *(mm/dd/yy)*: ___ / ___ / ___