HBV/HIV Enrollment Criteria

General Instructions

The Enrollment Criteria form lists the inclusion and exclusion criteria for the HBV/HIV Co-infected Ancillary Study. This form is to be completed after the patient information has been recorded on the Screening Log, the eligibility criteria listed on the Screening Log have been met, and the patient has provided written informed consent for study participation. This form should be completed when patient eligibility can be determined, most likely at the screening visit or very shortly after the screening visit.

Consent for the genetic component of the HBV/HIV Co-infected Ancillary Study is not required for participation in the HBV/HIV Co-infected Ancillary Study.

Consent for stored samples (serum, plasma, liver tissue) is required since many of the laboratory tests that are important to the ancillary study will be performed on stored samples at the HBRN central testing laboratory.

Specific Instructions

Patient ID**:**	Record the Patient ID in the top right hand corner.
Date of Determination:	Record the date (month/day/year) that patient eligibility is determined. Either the patient meets all inclusion criteria and none of the exclusion criteria (eligible) or the patient fails to meet at least one of the inclusion criteria or meets any of the exclusion criteria (ineligible).

Section I: Inclusion Criteria

	Check “Yes” or “No” to indicate if the patient meets each of the inclusion criteria. The response to all inclusion criteria must be YES for a patient to be eligible for participation in this study.
Age:	Check “Yes” if the patient is 18 years of age or older or check “No” if the patient is under 18 years of age at the time.
HIV positive:	Check “Yes” if the patient is HIV positive or has a history of a positive HIV RNA or check “No” if there is no test result to confirm that the patient is HIV positive.
HBsAg positive:	Check “Yes” if the patient is HBsAg positive or check “No” if there is no test result to confirm that the patient is HBsAg positive at the time.
Receiving anti-retroviral therapy for HBV or HIV:	Check “Yes” if the patient is currently receiving any type of anti-retroviral therapy for HBV or HIV or check “No” if the patient is not receiving anti-retroviral therapy for HBV or HIV.
Informed consent:	Check “Yes” if the patient has provided written informed consent to participate in this study or check “No” if consent has not been obtained.

Section II: Exclusion Criteria

	Check “Yes” or “No” to indicate if the patient meets the following exclusion criteria. The response to all exclusion criteria must be NO for a patient to be eligible for participation in this study.
Estimated life	Based on clinical judgment and the opinion of the study physician, check “No” if

Expectancy < 1 year

the patient is expected to live at least a year or more from the date of potential entrollment into the study or check “Yes” if the patient is expected to live less than one year from the date of the potential enrollment into the study.

Hepatic decompensation:

Check “No” if the patient does not have a history of hepatic decompensation. Check “Yes” if the patient has ever been diagnosed with hepatic decompensation defined as the presence of any of the following:

- Ascites or hepatic hydrothorax
- Variceal or portal hypertensive bleeding
- Hepatic encephalopathy
- Child-Turcotte-Pugh (CTP) score ≥ 7

A patient with acute hepatitis B and a CTP >7 may be enrolled as long as the patient is not in liver failure. The CTP score applies to patients with cirrhosis only.

CTP score is calculated using the algorithm below.

		Number of points		
Items	**Units**	**1**	**2**	**3**
Serum albumin	g/dL	>3.5	2.8-3.5	<2.8
Serum total bilirubin No Gilbert’s Syndrome No hemolytic diseases Not receiving Ribavirin	mg/dL	<2.0	2.0-3.0	>3.0
Serum total bilirubin Presence of Gilbert’s Syndrome Hemolytic disorder such as patients receiving Ribavirin*	mg/dL	<4.0	4.0-7.0	>7.0
INR		<1.7	1.7-2.3	>2.3
Ascites		None	Mild^	Severe‡
Encephalopathy		None	Mild^	Severe‡

Note that if, in the opinion of the investigator, the patient has Gilbert’s syndrome or a hemolytic disorder (e.g., patients receiving ribavirin) the level of the serum total bilirubin may be increased to as high as 3.99 mg/dL without considering the total bilirubin to be sufficiently elevated for the patient to receive a score of 2 in the CTP scoring system.

^ Mild means readily controlled by standard medical therapies.

‡ Severe means difficult to control or uncontrollable by optimal, maximally tolerated medical therapies.

The score is the sum of the scores for albumin, total bilirubin, INR, ascites and encephalopathy (range 5-15)**.**

Class A = 5-6
Class B = 7-9
Class C = 10-15

HCC:

Check “No” if the patient does not have a history and there is no known evidence of hepatocellular carcinoma (HCC). Check “Yes” if the patient has a diagnosis of HCC. The diagnosis of HCC will follow the AASLD guidelines.

Anti-HCV positive:	Check “No” if the patient is anti-HCV negative at screening or HCV RNA negative within 6 months prior to the baseline visit. If a historical biopsy is being used, the patient must have been HCV RNA negative at least 6 months prior to the time of the biopsy. Check “Yes” if the patient is HCV RNA positive within 6 months of the baseline visit (or HCV RNA positive within 6 months of the baseline biopsy).
Solid organ or bone marrow transplant:	Check “No” if the patient has not had a solid organ transplant or bone marrow transplant. Check “Yes” if the patient has had a solid organ transplant or bone marrow transplant.
Pregnant woman:	Check “No” if the patient tests negative for a pregnancy test or is known to not be pregnant (if a pregnancy test is not required). Check “Yes” if the patient is known to be pregnant or tests positive with a pregnancy test.
Contraindications to Liver biopsy:	Check “No” if the patient is willing and physically able (in the opinion of the study physician) to undergo a liver biopsy procedure at the start and end of the study. Check “Yes” if the patient has expressed or implied that they are not willing to undergo liver biopsy procedures as required per protocol or if there is some contraindication for a liver biopsy procedure in the opinion of the study physician. If the liver biopsy is performed as part of the screening evaluation, obtain unstained slides for the HBRN central pathologists readings and complete the Liver Biopsy Complications form. If a liver biopsy was performed in the past 3 years, provide the date of the most recent biopsy performed within the past 3 years and request slides. If any part of the biopsy date is unknown, record “Unk” for that field. **Every effort should be made to obtain slides for the central reading.** If possible, obtain slides that do not have to be returned to the local institution. If this is not possible, slides will be returned to the local institution after being read by the HBRN central pathologists.
Routine follow-up:	Check “No” if the there is no indication or reason to believe that the patient would be unwilling or unable to adhere to the routine follow-up schedule for the study protocol or to return per protocol for “special visits”. Check “Yes” if the patient has expressed or implied that they will be unable to adhere to the protocol schedule and you chose to exclude them from enrollment for this reason.
Other evidence for exclusion:	Check “No” if there is no other reason, in the opinion of the investigator, to exclude the patient from participation in the study. Check “Yes” and record the reason in the space provided if, in the opinion of the investigator, there is some medical, social, or other reason that the patient should not be enrolled in the Cohort Study.

The response to all inclusion criteria must be YES and all exclusion criteria must be NO for the patient to be eligible for participation in this study. If the patient is determined to be eligible, check “Yes” to the eligibility question at the bottom of the page. If the patient is not eligible for participation then check “No” and no additional study-related tests should be performed or data collection forms completed for the HBV/HIV Co-infected Ancillary study.