Screening Log

General Instructions

All HBsAg positive pediatric patients at least 6 months of age to <18 years of age seen in the clinic should be recorded on the Screening Log. The purpose of the log is to capture information on the number and types of HBsAg positive pediatric patients seen in the participating Hepatitis B Research Network (HBRN) centers. Patients do not need to be consented in order to capture the information for the Screening Log.

A patient permanently living outside of the U.S. or Canada at the time of enrollment should not be enrolled into the Cohort Study.

The Screening Log captures a minimal amount of demographic information on all HBsAg positive pediatric patients (6 months to <18 years) **actively screened** for participation in the Cohort Study, regardless of whether they are enrolled in the Cohort Study. One line of the log is completed for each patient screening. A patient may be screened more than once if they are not enrolled into the Cohort Study at the time of the initial screening. In the case of a patient rescreen, the screening information is recorded on the Screening Log more than once, using one row for each screening.

For the purposes of the HBRN, "actively screened" is defined as a patient seen in person. Chart review alone or telephone screening is not considered actively screened.

The Screening Log is to be kept at the clinical center in a secure locked file cabinet or office. The paper copy is never submitted to the Data Coordinating Center or any group outside your clinical center.

The clinical center is to keep a separate patient log to prevent a potential participant from being recorded on this log more than once, except in the instance of a rescreen, when a previously ineligible patient is screened again with the thought of enrolling that patient at the time of the rescreen.

Specific Instructions

Page:	Record the page number. Begin with page 1 and continue to increment the page number as needed.
Month/Year screened:	Record the month and two digit year that the patient is screened.
Year of birth:	Record the 4 digit year of birth.
Gender:	Circle "M" (male) or "F" (female) for patient gender.
Pregnant:	Check the box if the patient is pregnant at the time of screening.
Race:	Check the appropriate category to indicate the race of the patient. If the patient identifies with more than one race, check all that apply. White or Caucasian: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. Black or African-American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African-American". Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Native Hawaiian or Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

Other: If the patient's racial background is not listed, check "Other" and specify the patient's race in the space provided.

Check "Unknown" if the patient race is not known or the patient refuses to identify race.

Eligibility Criteria

Circle "Y" (yes) or "N" (no) for each of the eligibility criteria.

Hepatic decompensation: Circle "N" (no) if the patient does not have a history of hepatic decompensation. Circle "Y" (yes) if the patient has been diagnosed with hepatic decompensation, defined as the presence of any of the following (definitions for items provided below):

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

Ascites: Defined as an excess of fluid in the peritoneal cavity that is either mild, moderate or marked on ultrasound, or is progressive on serial physical examinations, or requires diuretic therapy. Ultrasound report of minimal fluid around the liver does not meet the definition.

Medical record must indicate the presence of ascites or diuretic usage and one of the following:

- Paracentesis lab report
- Liver U/S report
- Liver CT report
- Liver MRI report

Hepatic hydrothorax: ascites associated pleural effusion.

Variceal bleeding: defined as GI bleeding from varices present in the esophagus or stomach based on an endoscopy showing either:

- Direct evidence of variceal bleeding (bleeding varix, red wale sign)
- Moderate varices with no other site of bleeding identified and historical evidence for clinically significant upper GI bleeding.

Medical record must include an endoscopy report showing evidence of active or recurrent bleed within 48 hours of an episode.

Portal hypertensive bleeding: gastrointestinal bleeding associated with portal hypertension.

Hepatic encephalopathy: Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. Symptoms include changes in mental state,

consciousness, behavior and personality, decrease in performance of simple self-care tasks, or muscle spasms or rigidity. Also known as portal-systemic encephalopathy.

Medical record must indicate one of the following:

- Asterixis
- Clinical alteration in mental status with reversibility with therapy
- Two or more episodes of confusion consistent with encephalopathy

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: Circle "N" (no) if the patient does not have a history and there is no known evidence of hepatocellular carcinoma (HCC). Circle "Y" (yes) if the patient has been diagnosed with HCC. The definition of HCC will follow the AASLD guidelines.

Liver transplant: Circle "N" (no) if the patient has not had a liver transplant or "Y" (yes) if the patient has had a liver transplant.

HIV infection: Circle "N" (no) if the patient is not known to have HIV infection or "Y" (yes) if the patient is known to have HIV infection.

Current hepatitis B antiviral treatment: Circle “N” (no) if the patient is currently not taking antiviral treatment for hepatitis B. Circle “Y” (yes) if the patient is currently on an antiviral therapy for hepatitis B, which includes but is not limited to Entecavir, Telbivudine, Lamivudine, Adefovir, Tenofovir, Emtricitabine, and Truvada.

Cohort consent obtained: If “No” is indicated for all of the items listed, history of hepatic decompensation, history of HCC, history of liver transplantation, known HIV infection, and currently on therapy for HBV, then the patient is eligible for participation in the Cohort Study. **NOTE**: A pregnant female, on antiviral therapy for hepatitis B, is eligible to participate in the Cohort Study. Patients who are not eligible for participation according to any of the criteria listed above do not have to be approached to obtain informed consent.

Circle “Y” (yes) or “N” (no) to indicate if the caregiver provided informed consent and patient provided assent when age appropiate for participation in the Cohort Study. Circle “N/A” if a “Yes” response was recorded for any of the eligibility criteria: history of hepatic decompensation, history of HCC, history of liver transplantation, known HIV infection, currently on therapy for HBV (and not pregnant), or if the patient was not approached for the Cohort Study.

If the patient is approached but does not consent to study participation, then record the code that corresponds to the reason the patient did not provide consent.

If the patient was not approached for study participation because of a known medical condition that would make them ineligible, or the patient would not be a good candidate for the study based on the investigator's opinion, record “Patient not approached, clinically ineligible”.

If “Other” is recorded, specify the reason in the space provided.

Participant information: If the patient meets the eligibility criteria and provides informed consent for the Cohort Study and assent when age appropriate, a Patient ID will be assigned. If the patient does not meet the eligibility criteria or does not provide informed consent, a Patient ID will not be assigned.

Date consented: Record the date (month/day/year) of the first consent obtained for the Cohort Study.

Patient ID: Patients who are enrolled in the Cohort Study will be assigned a Patient ID. The Patient ID will be assigned by the HBRN Data Collection and Entry System after the data from the Screening Log have been submitted. After assigning a Patient ID, the system will prompt you to record that Patient ID on the log sheet.

Patients that are not enrolled in the study will not be assigned a Patient ID.

Rescreen: A patient may be screened more than once for participation in the Cohort Study. If a patient has been previously screened and not enrolled, and is then rescreened, with the intention of enrolling that patient, check the “Rescreen” box, regardless of whether the patient is enrolled at the time of the rescreen. Patients recorded on the Screening Log and not enrolled in the Cohort Study should not be recorded on the Screening Log again if they are not being “rescreened” with the intention of enrolling them into the Cohort Study.