Immunology Study
Enrollment Criteria (Adult)

General Instructions

The Immunology Study Enrollment Criteria form lists the inclusion and exclusion criteria for the Immunology Study. This form is to be completed after the patient has completed the baseline visit (exception is acute hepatitis or ALT flare patients at baseline) 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 Week 12 follow-up visit.

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.

Hepatitis B phenotype: Check "Yes" if (in the opinion of the investigator) the patient's HBV phenotype meets the criteria for one of the phenotypes defined below, at the time of enrollment into the Immunology Ancillary study. Otherwise check "No".

> If yes, check the box corresponding to the hepatitis B phenotype as determined at the time of enrollment into the Immunology Ancillary study. ***For those phenotypes that have criteria for both definite and probable, the definite criteria should be used to determine eligibility***.

Immune tolerant: Presence of HBsAg and HBeAg and normal ALT levels on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than 1,000,000 IU/mL.

HBeAg-positive chronic hepatitis: Definite: Presence of HBsAg and HBeAg and abnormal serum ALT levels (at least twice the ULN) on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than 10,000 IU/mL. Probable: Presence of HBsAg and HBeAg and HBV DNA greater than 10,000 IU/mL, but ALT levels between 1-2 times the ULN.

HBeAg-negative chronic hepatitis: Definite: Presence of HBsAg without HBeAg but with abnormal serum ALT levels (at least twice the ULN) on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than or equal to 1,000 IU/mL. Probable: Presence of HBsAg without HBeAg and HBV DNA greater than or equal to 1,000 IU/mL, but ALT levels between 1-2 times the ULN.

Inactive carrier: Definite: Presence of HBsAg without HBeAg and normal ALT levels on two occasions or more over a period of at least 6 months. HBV DNA levels of less than 1,000 IU/mL. Probable: Presence of HBsAg without HBeAg and HBV DNA between 1,000-10,000 IU/mL, but ALT levels normal.

Hepatitis B with ALT Flare (Chronic or Acute):

Chronic Hepatitis B: ALT test result ≥ 300 IU/L in males and ≥ 200 IU/L in females.

Acute Hepatitis B: Presence of HBsAg and IgM anti-HBc with serum ALT values greater than 300 IU/L and absence of known history of HBsAg positivity. Probable acute hepatitis B is when all above criteria are met except serum ALT is less than or equal to 300 IU/L or if there is any suspicion of chronic disease.

Note: When sample size enrollment is met in a phenotype, patients with that phenotype will no longer be enrolled into the Immunology Ancillary study. Enrollment is closed for the following phenotypes:

- HBeAg-negative chronic hepatitis (5/1/12)
- Acute hepatitis (3/1/13)
  - ***Acute hepatitis reopened for enrollment on 2/6/15***
- Inactive Carrier (2/27/14)

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.

Anemia: Based on the most recent hemoglobin and hematocrit tests performed: Check "No" if the patient does not have a hemoglobin result <10 or hematocrit <30. Check "Yes" if the patient has a hemoglobin result <10 or hematocrit result <30. A hemoglobin or hematocrit does not have to be performed for the purpose of this ancillary study but should be performed if clinically indicated or if they are necessary to determine eligibility in the opinion of the investigator.

Active medical: condition: Check "No" if the patient does not have an active medical condition that would make the patient unsuitable for the study. Check "Yes" if the patient has an active medical condition which includes but is not limited to congestive heart failure, chronic lung disease requiring oxygen, coronary artery disease with unstable angina, sepsis, or renal failure that would make the patient unsuitable for the study.

Autoimmune or immunosuppression: Check "No" if the patient does not have a known autoimmune disease and is not on any immunosuppressive therapy. Check "Yes" if the patient has a known autoimmune disease or is on immunosuppressive therapy.

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 Immunology 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. Samples are to be collected per the Immunology Study protocol. If the patient is not eligible for participation then check “No” and no samples are to be collected for the Immunology study.