Enrollment Criteria

General Instructions

The Enrollment Criteria form lists the inclusion and exclusion criteria for the Immune Active Trial. This form is to be completed when patient eligibility can be determined, most likely at the screening visit or sometime between the screening visit and the baseline visit, but definitely before the patient is randomized.

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 whether or not 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.

Note that the determination of patient age and the timeframe for the historical labs relate to the randomization date (also referred to as Day 0 or Baseline Visit).

HBV DNA results: record the two test results, date of test, and lower limit of detection used to determine HBV DNA inclusion criterion.

ALT results: record the two ALT test results and date of test used to determine ALT inclusion criterion.

Imaging within 28 weeks: record the date imaging was completed to determine inclusion criterion. Refer to the AASLD guidelines for HCC surveillance on the HBRN Study website: http://www.hepbnet.org/research/docsharing/?startFolder=%5CReference+Documents

Biopsy: record the Modified Ishak HAI score, Ishak score and date of biopsy used to determine histology criterion. The Modified Ishak HAI score is determined by the local consortium pathologist and is recorded on the Site Pathology Review (PRIA) form as the Total Score in Section II Inflammation.

Reliable (adequate) method of contraception: usually two methods of contraception are required. Abstinence may be considered to be a reliable method of contraception but the patient must be willing to document that "abstinence is the method of contraception" at each protocol visit, and if the patient becomes sexually active during the course of the treatment period then two methods of contraception are required.

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.

The following exclusion criteria require additional definitions:

History of alcohol or drug abuse: a history of alcohol or drug abuse (not use) within the 48 week period prior to randomization, in the opinion of the physician investigator.

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 IA Trial.

The physician investigator should review and sign the completed form for all patients who are considered to be eligible.