



## Baseline Evaluation - Investigator (Pediatric)

Patient ID \_\_\_ - \_\_\_ - \_\_\_ ID \_\_\_ - \_\_\_ - \_\_\_

Date of Evaluation: **DOEDATE**

This information is to be provided by the physician investigator immediately following completion of the baseline evaluation. The information is to reflect the opinion of the physician investigator based on information available at the time of the baseline evaluation.

Physician Investigator Initials: \_\_\_ **PIID** \_\_\_

### SECTION I: PHENOTYPE (refer to study definitions below)

1. Phenotype of patient (*check one*) **HBPHY**

- 1  Acute hepatitis B
- 2  Immune tolerant chronic hepatitis B
- 3  HBeAg positive chronic hepatitis B
- 4  HBeAg negative chronic hepatitis B
- 5  Inactive carrier state
- 6  Indeterminate

**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.

**Immune tolerant (definite):** 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:** 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.

**Indeterminate:** Does not fit into any of the above categories.

### SECTION II: HBV DURATION AND SOURCE

1. Estimated duration of HBV infection: **HBDUR** 1  Years 2  Months 3  Weeks  Unknown **HBDURT**

2. Presumed source of hepatitis B? (*check the most likely, check only one*) **SRCPI**

- |  |  |                                  |
|--|--|----------------------------------|
| 1 <input type="checkbox"/> Vertical transmission   | 6 <input type="checkbox"/> Medical/surgical    | <input type="checkbox"/> Unknown |
| 2 <input type="checkbox"/> Horizontal transmission | 7 <input type="checkbox"/> Transfusion         |                                  |
| 3 <input type="checkbox"/> Adult household contact | 8 <input type="checkbox"/> Injection drug use  |                                  |
| 4 <input type="checkbox"/> Sexually transmitted    | 9 <input type="checkbox"/> Intranasal drug use |                                  |
| 5 <input type="checkbox"/> Occupational            | 10 <input type="checkbox"/> Other _____        | <b>SRCPIS</b>                    |

3. Is the patient symptomatic of hepatitis B?  Yes  No  Unable to determine **HBSYMP**