



## Baseline Evaluation - Investigator (Adult)

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: RISK ASSESSMENT

**SEXCONTB**

- Has the patient ever had sexual contact with a person who had hepatitis B? ☐ Yes ☐ No ☐ Unknown
- Has the patient ever been diagnosed by a doctor (or other health professional) with any sexually transmitted disease such as gonorrhea, syphilis, trichomonas, chlamydia or genital warts?  
☐ Yes ☐ No ☐ Unknown **STD**

If Yes, how many times (all together) has the patient had a sexually transmitted disease?

1 ☐ 1 time 2 ☐ 2-4 times 3 ☐ More than 4 times ☐ Unknown **STDNUM**

- What is the best estimate of the total number of persons of the opposite sex that the patient has had sexual intercourse with even once (including their partner): **SEXPNUM** ☐ Unknown
- Has the patient ever had sexual intercourse with a person of the same sex?  
☐ Yes ☐ No ☐ Unknown **SAMESEX**

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

- Phenotype of patient (check one) **HBPHY**

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Acute hepatitis B                   | 4 <input type="checkbox"/> HBeAg negative chronic hepatitis B |
| 2 <input type="checkbox"/> Immune tolerant chronic hepatitis B | 5 <input type="checkbox"/> Inactive carrier state             |
| 3 <input type="checkbox"/> HBeAg positive chronic hepatitis B  | 6 <input type="checkbox"/> Indeterminate                      |
|  | 7 <input type="checkbox"/> Cannot determine (HIV Coinf only)  |

**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 III: HBV DURATION AND SOURCE

- Estimated duration of HBV infection: **HB DUR** 1 ☐ Years 2 ☐ Months 3 ☐ Weeks ☐ Unknown **HB DURT**
- Presumed source of hepatitis B? (check the most likely, check only one) **SRCP**  

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>
- Is the patient symptomatic of hepatitis B? ☐ Yes ☐ No ☐ Unable to determine **HBSYMP**

### SECTION IV: HBV/HIV COINFECTED ANCILLARY STUDY ONLY

- Estimated duration of HIV infection: **HIV DUR** 1 ☐ Years 2 ☐ Months 3 ☐ Weeks ☐ Unknown **HIV DURT**
- Has the patient ever had sexual contact with a person who had HIV? ☐ Yes ☐ No ☐ Unk **SEXCONTV**
- Presumed source of HIV? (check the most likely, check only one) **HIV SRC**  

1 <input type="checkbox"/> Vertical transmission	6 <input type="checkbox"/> Medical/surgical	10 <input type="checkbox"/> Other _____	<b>HIV SRC S</b>
4 <input type="checkbox"/> Sexually transmitted	7 <input type="checkbox"/> Transfusion	<input type="checkbox"/> Unknown	
5 <input type="checkbox"/> Occupational	8 <input type="checkbox"/> Injection drug use		