Enrollment Criteria (Pediatric)

Patient ID __ __ - __ **ID** __ - __ __ __

Date of Determination: **ERLDATE**

SECTION I: INCLUSION CRITERIA Check if rescreen: ☐ **RSC**

1. Enrolled in the HBRN Cohort Study or completed the necessary components of the Cohort baseline evaluation by the end of the baseline visit for this trial. **INCOHORT**	☐ Yes	☐ No
2. Patient is 3 to <18 years of age at the time of the baseline visit (day 0). . **INAGEIT**	☐ Yes	☐ No
3. Documented chronic HBV infection as evidenced by detection of HBsAg in serum for ≥ 24 weeks prior to baseline visit or positive HBsAg and negative anti-HBc IgM within 24 weeks of baseline visit. **INCHB**	☐ Yes	☐ No
4. Presence of HBeAg in serum at the last screening visit within 6 weeks of baseline visit **INHBE**	☐ Yes	☐ No
5. Serum HBV DNA level >10^7 IU/mL on at least two occasions at least 12 weeks apart during the 52 weeks before baseline visit. One of the two HBV DNA levels must be within 6 weeks of the baseline visit HBV DNA results: **INDNA** Level (IU/mL): **BDNA1** **BDNA2** Date *(mm/dd/yy)*: **BDNA1M/D/Y** **BDNA2M/D/Y** Lower limit of detection: **BDNALL1** **BDNALL2**	☐ Yes	☐ No
6. ALT ≤ 60 IU/L for males or ≤ 40 IU/L for females, measured on at least 2 occasions, at screening (within 6 weeks prior to baseline visit) and another that is at least 12 weeks prior to the screening visit and within the 52 weeks prior to the baseline visit **INALT** ALT results: ALT IU/L **ALT1** **ALT2** Date *(mm/dd/yy)* **ALT1M/D/Y** **ALT2M/D/Y**	☐ Yes	☐ No
7. Compensated liver disease, with normal total bilirubin (except if Gilbert's syndrome), direct bilirubin ≤ 0.5 mg/dL, INR ≤ 1.5, and serum albumin ≥ 3.5 g/dL. **INBILI**	☐ Yes	☐ No
8. Creatinine clearance ≥ 90mL/min. **INCRCL**	☐ Yes	☐ No
9. Absence of hepatocellular carcinoma on liver ultrasound in the past 52 weeks. **NEGUS** Imaging in past 52 weeks **IMAGM/D/Y** *(mm/dd/yy)*	☐ Yes	☐ No
10. Parent/guardian provides informed consent and willing to adhere to the requirements of the study. **ITCONS** If No, reason(s) informed consent not provided *(check all that apply)*: ☐ Entecavir side effects **ENTSE** ☐ Pegylated interferon side effects **PEGSE** ☐ Blood draw frequency or volume **BLD** ☐ Frequency of visits **VISIT** ☐ Patient move **MOVE** ☐ Other **NCOTH**: _____**NCOTHS**_____	☐ Yes	☐ No

SECTION II: EXCLUSION CRITERIA

1. Presence of infection at screening with HCV-RNA or anti-HCV, anti-HDV, or HIV. **OTHVIRDX**	☐ Yes	☐ No
2. Presence of another cause of liver disease or HCC (serum alpha-fetoprotein > 50ng/mL). **OTHLVDX**	☐ Yes	☐ No
3. Evidence of decompensated liver disease (Childs B-C). **ITHDC**	☐ Yes	☐ No or N/A
4. History or another evidence of a medical condition associated with chronic liver disease (e.g., hemochromatosis, autoimmune hepatitis, alcoholic liver disease, toxin exposures). **EXCHLIV**	☐ Yes	☐ No or N/A
5. Female patient who is pregnant or breastfeeding. **EXPRG**	☐ Yes	☐ No or N/A
6. Adolescent females unwilling or unable to use an acceptable method of contraception if sexually active during the treatment period. **EXCONT** ☐ check if patient not of child bearing potential **NOCHILD**	☐ Yes	☐ No or N/A
7. Children currently breastfeeding while their mother is taking lamivudine, or those who were exposed to lamivudine for ≥ 24 weeks via maternal lamivudine treatment during pregnancy and/or while breastfeeding. **EXBRF**	☐ Yes	☐ No

8. Malignancy or other significant medical or psychiatric illness which, in the opinion of a study physician, may interfere with participant treatment, assessment or compliance with the study protocol. **EXMEDDX**	☐ Yes	☐ No
9. Previous liver or other organ transplantation including engrafted bone marrow transplant. **ORGANTX**	☐ Yes	☐ No
10. Hematological abnormalities during the screening period that contraindicate full dosing with study drugs, e.g. absolute neutrophil count < 1.5 x 10^9 cells/L or platelet count < 120 x 10^9 cells/L. **EXLAB**	☐ Yes	☐ No
11. Known allergy to study drugs; peginterferon alpha-2a or entecavir. . **EXALGY**	☐ Yes	☐ No
12. Treatment with systemic acyclovir or famciclovir within the previous 6 months. **ACYTX**	☐ Yes	☐ No
13. Need for ongoing use of any antivirals with activity against HBV during the course of the study or history of receiving treatment for HBV. **ANTIVTX**	☐ Yes	☐ No
14. Any use of illegal drugs OR use of alcoholic beverages which in the opinion of a study physician is sufficient to prevent adequate compliance with study procedures or increase the risk of pancreatitis or hepatotoxicity. **EXALC**	☐ Yes	☐ No
15. History of immunologically mediated disease (e.g. inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune haemolytic anemia, scleroderma, severe psoriasis, rheumatoid arthritis). **EXIMMDX**	☐ Yes	☐ No
16. History or other evidence of bleeding from esophageal varices or consistent with decompensated liver disease. **EXVARC**	☐ Yes	☐ No
17. History or other evidence of chronic pulmonary disease associated with functional limitation. **EXPULM**	☐ Yes	☐ No
18. History of significant cardiovascular diseases. **EXCARDV**	☐ Yes	☐ No
19. History of severe seizure disorder or current anticonvulsant use. **EXSZR**	☐ Yes	☐ No
20. History of other evidence of severe retinopathy. **EXRTN**	☐ Yes	☐ No
21. History of thyroid disease poorly controlled on prescribed medications. Participants with elevated thyroid stimulating hormone concentrations with elevation of antibodies to thyroid peroxidase and any clinical manifestations of thyroid disease are excluded. **EXTHY**	☐ Yes	☐ No
22. Concomitant use or use during ≤ 6 months prior to the first dose of study drug of anti-neoplastic, immunosuppressive, nephrotoxic or hepatotoxic medication, methadone, theophylline, or medications that may affect renal excretion or hepatic metabolism are not permitted. **IMMTX**	☐ Yes	☐ No
23. Concomitant use of complementary or alternative medications purported to have antiviral activity. **HERBAL**	☐ Yes	☐ No
24. A participant may not be co-enrolled in another clinical trial where an investigational drug is administered. **INVRX**	☐ Yes	☐ No
25. Any other condition or situation that, in the opinion of a study physician, would make the patient unsuitable for enrollment or could interfere with the patient participating in and completing the study? **PIOTH** If Yes, specify _____ **PIOTHS**	☐ Yes	☐ No

If the responses to all inclusion criteria are YES and all exclusion criteria are NO, the patient is eligible to participate in the Immune Tolerant Trial.

Is the patient eligible to participate in the Immune Tolerant trial? ☐ Yes ☐ No **ENROLLIT**

Investigator signature: _____

Data collector initials: **DCID**

Date data collection completed *(mm/dd/yy)*: **DCM/DCD/DCY**