Discontinuation of Treatment or Study (Pediatric)

Patient ID __ __ - __ **ID** __ - __ __ __
Date Form Completed: **DFCDATE**

Instruction: *Complete this form when the patient prematurely discontinues study medication, study participation or both.*

1. Time period: 1 ☐ Treatment 2 ☐ Follow-up **TIMEP**
2. Is this a discontinuation in study medication and/or study participation? *(check all that apply)*
   - ☐ Study medication (complete Section I) **SMED**
   - ☐ Study participation (complete Section II) **SPART**

SECTION I: STUDY MEDICATION

1. Reason(s) for discontinuing study medication(s) *(check all that apply)*:
   - ☐ Withdrawal of informed consent **RMWCONS**
   - ☐ Neutropenia **RMNEUT**
   - ☐ Hepatic decompensation **RMHDC**
   - ☐ Autoimmune hepatitis **RMAUTO**
   - ☐ Pregnancy **RMPREG**
   - ☐ Psoriatic lesion **RMPSOR**
   - ☐ Hypoglycemia, hyperglycemia or diabetes mellitus **RMDIAB**
   - ☐ Thyroid disorder/dysfunction **RMTHYD**
   - ☐ Depression or other psychiatric or mood disorder **RMPSY**
   - ☐ Hypersensitivity reaction **RMHYPS**
   - ☐ Pulmonary function impairment **RMPF**
   - ☐ Anemia **RMANEM**
   - ☐ Renal function impairment **RMRF**
   - ☐ Ophthalmologic disorder **RMOPH**
   - ☐ Grade IV toxicity **RMTOX4**
   - ☐ Virological non-response **RMVNRSP**
   - ☐ Virological breakthrough **RMVBRK**
   - ☐ Adverse event other than those listed **RMAE**, specify _____**RMAES**_____
   - ☐ Investigator discretion **RMINV**, explain ____**RMINVS**_____
2. Date of last dose of entecavir *(mm/dd/yy)*: **LDEM** / **LDED** / **LDEY**
3. Date of last dose of peginterferon *(mm/dd/yy)*: **LDPM** / **LDPD** / **LDPY**

SECTION II: STUDY PARTICIPATION

1. Reason(s) for discontinuing study participation *(check all that apply)*:
   - ☐ Patient lost to follow-up **RSLFUP**
   - ☐ Withdrawal of informed consent **RSWCONS**
   - ☐ Patient on alternate therapy for HBV **RSHBVTX**
   - ☐ Investigator discretion **RSINV**, explain _____**RSINVS**_____
   - ☐ Other **RSOTH**, specify _____**RSOTHS**_____
2. Date withdrawn (or considered to be withdrawn) *(mm/dd/yy)*: **WDM** / **WDD** / **WDY**
3. Date of last contact *(mm/dd/yy)*: **LCM** / **LCD** / **LCY**