



## Off Protocol Form (Pediatric)

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

Date Form Completed: **DFCDATE**

**Instruction:** Complete this form to report a deviation from protocol, at the time that the occurrence becomes known.

1. Was the deviation related to (check all that apply):

- Enrollment (complete Section I) **DEVENRL**  Protocol Visits (complete Section III) **DEVPV**  
 Randomization (complete Section II) **DEVRAND**  Biospecimens (complete Section IV) **DEVBIOS**

**SECTION I: ENROLLMENT** (check all that apply):

- Ineligible patient enrolled **EINELIG**  
 Initial supply of study medication not dispensed to patient at Baseline visit **EDISPEN**  
Reason: \_\_\_\_\_ **EDISPENS**  
 Initial dose of study medication not started on time per protocol **EDRGST**  
Date initial dose was taken (mm/dd/yy): **EDRGSTM** / **EDRGSTD** / **EDRGSTY**  
 Initial dose of study medication not per protocol **EINTDOSE**  
Starting dose of study medication:  
Entecavir **EIDENTEC** 1  mL 2  mg **EIDENTU**  
Peginterferon **EIDPEG** µg  
 Screening assessments were done more than 6 weeks prior to randomization **ESCREEN**

**SECTION II: RANDOMIZATION** (check all that apply):

- Ineligible patient randomized **RINELIG**  
 Patient randomized under incorrect Patient ID **RPTID**  
 Patient randomized according to wrong stratum **RSTRAT**  
Specify correct stratum:  
Center (see codes): \_\_\_\_\_ **RCENT**  
Age: 1  3 to 12 years 2  13 to <18 years 3  18 to 30 years 4  >30 to 40 years **RAGE**  
 Patient randomization performed prematurely (e.g. prior to completing baseline evaluation) **RPREMAT**

**SECTION III: PROTOCOL VISITS** (check all that apply):

- Component(s) of protocol visit not completed in person per protocol (check all that apply): **NOINP**  
 VEPIT: Visit Evaluation **VE**  
 SAPIT: Symptom Assessment **SA**  
 CIPIT: CDI Questionnaire **CDI**  
 CPPIT/CCPIT: CHQ Questionnaire **CHQ**  
 HBPIIT: Health Behavior Questionnaire **HB**  
Reason component(s) not completed in person: \_\_\_\_\_ **NOINPR** \_\_\_\_\_  
Method of data collection for forms not completed in person (check all that apply):  
 Telephone **PHONE**  Other **METHO** \_\_\_\_\_ **METHOS** \_\_\_\_\_  
Protocol timepoint (see codes): \_\_\_\_\_ **TMPT**

**SECTION IV: BIOSPECIMENS** (check all that apply):

- Test result from local rather than central lab used for study purpose **BLOCAL**