Off Protocol Form

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

Date Form Completed: **DFCDATE**

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

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

DEVENRL ☐ Enrollment (complete Section I)
DEVRAND ☐ Randomization (complete Section II)
DEVPV ☐ Protocol Visits (complete Section III)
☐ Biospecimens (complete Section IV) **DEVBIOS**
☐ Treatment Discontinuation (Week 192) or Reinitiation of Study Drug (complete Section V) **DEVTX**

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: _____**EDISPEN**_____

☐ 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: Tenofovir **EIDTEN** mg Peginterferon **EIDPEG** µg

☐ Screening assessments were done more than 8 weeks prior to randomization **ESCREEN**

☐ Other, specify: **EOTHR** _____**EOTHRS**_____

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** ___ HBeAg status: 1 ☐ positive 2 ☐ negative **RHBE**

Genotype: 1 ☐ A 2 ☐ other than A **RGENO** Cirrhosis: 1 ☐ present 2 ☐ absent **RCIRR**

☐ Patient randomization performed prematurely (e.g. prior to completing baseline evaluation) **RPREMAT**

☐ Other, specify: **ROTHR** _____**ROTHRS**_____

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

☐ Component(s) of protocol visit not completed in person per protocol *(check all that apply)*: **NOINP**

☐ VEIA: Visit Evaluation **VE** ☐ QLIA: Quality of Life Questionnaire **QL**

☐ SAIA: Symptom Assessment **SA** ☐ FQIA: Fatigue Questionnaire **FQ**

☐ CDIA: CES-D **CD**

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**

☐ Other, specify: **PVOTHR** _____**PVOTHRS**_____

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

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

SECTION V: TREATMENT DISCONTINUATION (WEEK 192) OR REINITIATION OF STUDY DRUG STXDEV

1 ☐ Discontinuation of study drug **DCSDDEV**

1 ☐ Eligible but study drug not discontinued

2 ☐ Not eligible but study drug discontinued

3 ☐ Other, specify:_____**DCSDDEVOS**___

2 ☐ Reinitiation of HBV treatment **RETXDEV**

1 ☐ Eligible to restart treatment but not restarted

2 ☐ Not eligible to restart treatment but restarted

3 ☐ Other, specify:_____**RETXDEVOS**_____