



Baseline Evaluation (Pediatric)

Patient ID ___ - ___ ID ___ - ___

Date of Evaluation: **DOEDATE**

SECTION I: ADVERSE EFFECTS

1. Does the patient currently have any of the following:

	Yes	No		Yes	No
a. Fatigue FATIG	<input type="checkbox"/>	<input type="checkbox"/>	l. Joint aches JOINT	<input type="checkbox"/>	<input type="checkbox"/>
b. Trouble sleeping TSLP	<input type="checkbox"/>	<input type="checkbox"/>	m. Diarrhea DIARR	<input type="checkbox"/>	<input type="checkbox"/>
c. Headache HEADACH	<input type="checkbox"/>	<input type="checkbox"/>	n. Vomiting VOMIT	<input type="checkbox"/>	<input type="checkbox"/>
d. Dizziness DIZZ	<input type="checkbox"/>	<input type="checkbox"/>	o. Upset stomach USTOM	<input type="checkbox"/>	<input type="checkbox"/>
e. Depression DEPRESS	<input type="checkbox"/>	<input type="checkbox"/>	p. Muscle pain MUSPN	<input type="checkbox"/>	<input type="checkbox"/>
f. Weight loss (unintentional) WGTLOSS	<input type="checkbox"/>	<input type="checkbox"/>	q. Rash RASH	<input type="checkbox"/>	<input type="checkbox"/>
g. Decreased appetite DAPP	<input type="checkbox"/>	<input type="checkbox"/>	r. Skin irritation SKIN	<input type="checkbox"/>	<input type="checkbox"/>
h. Vision problems VISION	<input type="checkbox"/>	<input type="checkbox"/>	s. Cold/Flu-like symptoms FLU	<input type="checkbox"/>	<input type="checkbox"/>
i. Nausea NAUS	<input type="checkbox"/>	<input type="checkbox"/>	t. Hair loss FLU	<input type="checkbox"/>	<input type="checkbox"/>
j. Upper abdominal pain ADPAIN	<input type="checkbox"/>	<input type="checkbox"/>	u. Other SYMOTH	<input type="checkbox"/>	<input type="checkbox"/>
k. Breathing problems BREATH	<input type="checkbox"/>	<input type="checkbox"/>	If yes, specify: SYMOTHS		

2. Has the patient experienced any adverse events (reportable at the level of detail of an adverse event), since the last protocol visit? **AE**

- Yes (Complete an Adverse Events form, if SAE complete the MedWatch form too)
- No

SECTION II: CONCOMITANT MEDICATIONS

- Has there been any change (start or stop) in prescription medications since the last protocol visit? **CONMED**
 Yes No If Yes, update the Concomitant Medication Log
- Is the patient currently taking any herbs, "natural" or herbal medications? **MEDHERB** Yes No Unknown
- Is the patient currently taking vitamins or minerals? Yes No Unknown **MEDVIT**
If Yes, (check all that apply)
 Multi-vitamin **VITMULT** Vitamin D **VITD** Vitamin E **VITE** Folate **VITFOL** Iron **VITFE** Calcium **VITCA** Other **VITOTH**

SECTION III: STUDY MEDICATION (do not complete for Control patients)

Confirm acceptable method of contraception, when applicable

- Was counseling on adherence provided during visit? **MATI** Yes No
- Was study drug (entecavir) dispensed? Yes No **DRGDSP** If yes, complete the Study Drug Log
If No, complete the Off Protocol form
- Total daily dose of entecavir: **ETVDOSE** 1 mL (solution) 2 mg (tablet) **ETVUNIT**

SECTION IV: PHYSICAL ASSESSMENT

- Height **HGT** 1 inches 2 cm **HINCM** Not done
- Weight: **WGT** 1 lbs. 2 kg **WLBKG** Not done
- Blood pressure: **BPS / BPD** mmHg Not done

SECTION V: BIOSPECIMENS

- Were samples obtained at this visit? Yes No **BIOSPEC**
If Yes, (check all that apply): NIDDK repository **NIDDKR** Central lab **CLAB** Genetics **GEN** Immunology study **IMM**

SECTION VI: TANNER STAGE

Instructions: Transcribe responses from the Tanner Stage questionnaire to the items below. If the patient is not of age to complete the Tanner Stage questionnaire, check "Not done".

- TANPHY** 1. Physical growth: 1 I 2 II 3 III 4 IV 5 V Unknown Prefer not to answer Not done
- TANPUB** 2. Pubic hair growth: 1 I 2 II 3 III 4 IV 5 V Unknown Prefer not to answer Not done

Data collector initials: **DCID** Date data collection completed (mm/dd/yy): **DCM / DCD / DCY**