



	Protocol Visits					ALT Flare [†]	HBe or HBs Loss	Liver Biopsy	Delayed Baseline Biopsy ^	Pregnancy [‡]
	Screen/ Baseline*	Year 1		Years 2-6						
		Week 24	Week 48*	Weeks 72,120,168	Weeks 96,144,192*					
SL: Screening Log	CC									
EH: HBV/HIV Enrollment Criteria	CC									
BC: Baseline Eval - Coordinator	CC									
BH: HBV/HIV Baseline Eval	CC									
AH: Antiviral Therapy Log		As needed				CC	CC	CC	CC	CC
OI: Opportunistic Infections Log		As needed							CC	
BP: Baseline Eval – Patient	PT									
BI: Baseline Eval – Investigator	PI									
QL: Quality of Life	PT		PT		PT				PT	
SA: Symptom Assessment	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT
FQ: Fatigue Questionnaire ^{††}	PT				PT				PT	
AU: AUDIT	PT		PT		PT				PT	
FF: Follow-up Evaluation		CC	CC	CC					CC	
FH: HBV/HIV Follow-Up (SV) Eval		CC	CC	CC	CC	CC	CC	CC	CC	CC
SV: Special Visit form		As needed				CC	CC	CC		CC
FB: Fibroscan	CC		CC		CC				CC	
FR: ALT Flare Resolution		As needed - at resolution of ALT flare				PI				
LB: Liver Biopsy [^]	CC	Week 192 and as clinically indicated						CC	CC	
FE: Follow-Up Events		As needed				CC	CC			
HC: HCC Form		As needed								
PQ: Pregnancy Questionnaire	CC									
PF: Pregnancy Follow-up		As needed – 12, 24, and 72 weeks post delivery								CC

All samples for this study are processed per the sample collection protocol, stored locally, and then batch shipped to the NIDDK Repository:

Genetics, whole blood (ml) #	5									
EDTA, whole blood (ml) #	10		10		10	10	10	10	10	10
SST, whole blood (ml), red or gold top #	30	20	30	20	30	10	10	10	30	10
Hornet, whole blood (ml), red/yellow top #	9				9 (weeks 96 & 192)					

* Obtain fasting labs at baseline and annual visits. If a special visit occurs within the window of an annual visit, complete the data forms, self-assessment questionnaires, and blood volumes required for the annual visit (if the annual visit has not already been completed)

[†] Acute hepatitis patients: follow ALT flare schedule for Special Visits and sample collection. FE and FR forms are not completed.

[‡] When a pregnancy visit is completed as a Special Visit the sample collection volume is left to the discretion of the investigator.

^{††} Completed at Baseline and Weeks 96 and 192.

[^] If biopsy is performed at a time other than screening (within 36 months prior to enrollment) or Week 192, complete the forms under the “Liver Biopsy” column. If the baseline biopsy is performed more than 12 weeks after the baseline visit, complete the forms indicated under “Delayed Baseline Biopsy” column.

Collect sample if patient consent provided.

CC	Clinical Coordinator
PT	Patient
PI	Physician Investigator



Adult Questionnaires - Translations

Questionnaire	Translations	Interpreter/Assistance Allowed*
Baseline Evaluation – Patient	Spanish Chinese Korean	Yes
Symptom Assessment	Spanish Chinese Korean	Yes
Quality of Life	Spanish Chinese Korean Vietnamese	Yes
Health Behavior	Spanish Chinese Korean	Yes
Fatigue Questionnaire	Spanish	No
CES-D	-	Yes
AUDIT	-	Yes

*Best practice for non-English reading patients - if the questionnaire is available in their language the patient should be encouraged to complete the questionnaire in that language on their own.