



Follow-Up 12-Week Evaluation (Adult)

General Instructions

The Follow-up Week 12 Evaluation form is completed at the Week 12 protocol timepoint of the Cohort Study. This visit consists of limited laboratory data and the collection of samples for storage.

If the baseline evaluation is completed in more than one visit, and all components of the baseline evaluation are not completed by the time of the Week 12 visit, the baseline evaluation must be completed at the Week 12 visit. Refer to the Cohort Study protocol for a list of the baseline evaluation components that may be completed after the initial baseline visit. Fasting labs and the genetic sample are two items that may oftentimes be completed at the Week 12 visit. Regardless of whether the baseline evaluation is completed at the time of the Week 12 evaluation, this form must be completed at the Week 12 visit.

There is a two (2) week window on either side of the 12 week follow-up evaluation date. However, information should be captured even when the evaluation is performed outside of this window.

Specific Instructions

Patient ID: Record the Patient ID number in the top right hand corner.

Date of Evaluation: Record the date (month/day/year) of the evaluation visit.

Section I: Tests

ALT: (1) Record the ALT result completed at the time of week 12 visit.
(2) Record the date (month/day/year) the sample was obtained or check "Not done" if the test was not performed.
(3) Record the lower and upper reference range of normal.

HBV DNA level: (1) Record the DNA level obtained at the time of the Week 12 visit. If the test was not performed, check "Not Done".
(2) Record the date the sample was obtained. If any piece of the date is unknown, record "Unk" in that field.
(3) Check "IU/mL" or "copies/mL" to indicate the unit of measure.
(4) Record the lower limit of detection for the test.

Section II: Biospecimens

Consent: Check "Obtained", "Refused", or "Not attempted at this visit" to indicate if the patient provided informed consent to obtain samples for research purposes for each of the following:

- i. Serum/plasma for research/storage
- ii. Liver tissue for research/storage
- iii. Genetics sample
- iv. Immunology study

Samples obtained: Check "NIDDK Repository (serum/plasma)", "Genetics", "Immunology study", or "Central Lab" to indicate which samples were obtained at the baseline visit. If no samples were collected, check "None".