Baseline Evaluation (Adult)

General Instructions

The Baseline Evaluation form is completed at the time of enrollment in the HBRN Cohort Study, following determination that the patient meets all enrollment criteria and provides informed consent. The baseline visit may be completed in two visits with the second baseline visit occurring before, or at the time of, the 12 week follow-up visit.

This form captures information obtained from a combination of sources - patient interview, medical record review, and a physical exam. When information in the medical record conflicts with information provided by the patient, the medical record is normally considered to be the accurate source, although there may be instances when the information provided by the patient is more up to date or accurate. In this instance, the information provided by the patient may be used.

Information for the diagnostic, serology, virology, and laboratory sections of the form should be obtained from the patient's medical record.

The coordinator is responsible for obtaining the information captured on this form. In non-English speaking patients, the interview may be performed through a certified interpreter. While a trained translator is preferred, a family member or friend of the patient (who speaks fluent English and the native language of the patient) may be acceptable for this role, as determined on an individual basis.

IMPORTANT: The patient must be fasting for the baseline visit. A 12 hour fast is optimal but at least 8 hours is acceptable.

Refer to the HBRN Cohort Codebook for items that require coded responses.

Specific Instructions

Patient ID**:** Record the Patient ID number in the top right hand corner of each page.

Date of Evaluation: Record the date (month/day/year) that corresponds to the baseline visit.

Screening Log Reference Page: Record the page number from the Screening Log that corresponds with the Patient ID.

Line: Record the line number from the Screening Log that corresponds with the Patient ID.

Section I: Demographics

Country of birth: (1) Record the code or country where the patient was born. If the country is not available or unknown, check "Unknown".

(2) If the patient was not born in the United States or Canada, record the year the patient immigrated to the United States or Canada. If the year is not available or is unknown, check "Unknown".

Country of parents: (1) Record the code or country where the patient's biological mother was born. If the country is not available or unknown, check "Unknown".

(2) Record the code or country where the patient's biological father was born. If the country is not available or unknown, check "Unknown".

Education level: Record the highest level of education completed by the patient. Record "Some college, no degree" if the patient was enrolled, but did not complete, a program for an Associate's or Bachelor's degree; do not include if patient was enrolled in a certificate only program. If the patient completed high school in conjunction with a certificate or equivalence from a vocational or technical school, with no higher education, check "Vocational or Technical School". If the patient refuses to answer the question, then record "Prefer not to answer".

Employment status:

(1) Record the current employment status of the patient. If the patient indicates that they are receiving disability or social security and not retired, record "Not currently employed, not retired". If the current employment status is not included on the list, check "other" and specify the current employment status in the space provided. If the patient refuses to answer the question, then record "Prefer not to answer".

(2) If the patient has a full-time [1] or part-time [2], paying job, answer questions 4.1 and 4.2.

Question 4.1: Check "Yes" if the patient is employed outside of the home. If not, check "No".

Question 4.2: Check "Yes" if the patient has had to reduce the number of hours worked per week due to his/her hepatitis B. If not, check "No".

(3) If the patient is a homemaker [3], not currently employed (retired) [4], or not currently employed (not retired) [5], answer question 4.3.

Question 4.3: Check "Yes" if the patient stopped working due to his/her hepatitis B. If not, check "No".

(4) If other [6] work status, complete the appropriate questions, 4.1 and 4.2 or 4.3, pertaining to the patient's current work status.

Insurance: Record the patient's current method of insurance. If the patient has more than one type of insurance coverage, check all that apply. If the patient refuses to answer the question, then record "Prefer not to answer".

Medicaid: State (public) administered health insurance program.

Medicare: Administered through The Centers for Medicare & Medicaid Services (CMS). Medicare is a health insurance program for people age 65 or older, some disabled people under age 65, and people of all ages with End-Stage Renal Disease (permanent kidney failure treated with dialysis or a transplant).

Tricare: Administered through the United States Department of Defense Military Health System. Tricare is a health insurance program for military personnel, military retirees, and dependents.

Government (not Medicaid/Medicare/Tricare): Other state or federal (U.S. or Canada) sponsored health insurance programs not affiliated with Medicaid, Medicare or Tricare.

Private: Administered through independent companies, contributed to by the individual or as a dependent, and may or may not be provided through an employer.

Other: Type of insurance is not included in the list provided. If other, specify the method of insurance in the space provided.

None/self pay: Patient does not have any health insurance coverage and/or pays out of pocket.

Section II: Family History

Check "Yes", "No", or "Unknown" for each item to indicate whether or not any of the patient's family members, biological family members only, have been diagnosed or told by a doctor that they have chronic hepatitis B, liver cancer, or diabetes. For each item that is marked "Yes", record the family member(s) to which the condition applies.

Section III: Medical History

Check "Yes", "No", or "Unknown" for each condition listed to indicate whether or not the patient has been diagnosed or told by a doctor that they have the condition, or is receiving treatment for the condition.

Diabetes: Juvenile (Type 1) or Type II onset diabetes, regardless of treatment (e.g. diet, exercise, oral medication, insulin). Gestational diabetes should not be captured here. If a pregnant woman is diagnosed with gestational diabetes check "No" but record any medications prescribed for the gestational diabetes in the medication section.

Hypertension: is normally diagnosed when a blood pressure of $\geq$ 140 systolic or $\geq$ 90 diastolic is noted on two separate occasions, or if the patient is currently on antihypertensive medication.

Hyperlipidemia: Blood level elevation of lipids such as cholesterol, cholesterol esters, phospholipids and triglycerides, or on medication to lower these levels.

Infections: HCV: documented positive anti-HCV test.

HDV: documented positive anti-HDV test.

Other liver disease: Other liver disease to be determined by the physician investigators:

Alcoholic: liver damage due to alcohol use.

Non-alcoholic fatty liver disease: fat accumulation in the liver not associated with alcohol use.

Autoimmune: inflammation of the liver due to the immune system. Patient should have a documented diagnosis from a doctor and corresponding auto-antibody tests.

Genetic/metabolic: liver diseases that are inherited or related to the metabolism of proteins or metals in the liver.

Cirrhosis: The diagnosis of cirrhosis must be confirmed by liver histology or clinical criteria which consist of any evidence of hepatic decompensation or the presence of at least two of the following: splenomegaly, nodular liver (documented by CT, MRI or liver ultrasound report), or platelet count below 120,000/mm^3 near time of diagnosis.
The protocol follow-up schedule does not change for patients diagnosed with cirrhosis however, these patients should be followed according to the current AASLD guideline for surveillance and early detection of HCC, consisting of ultrasonographic examination every 24 weeks and AFP tests. **Complete a Follow-Up Event (FE) form for participants with a diagnosis of cirrhosis at the baseline evaluation.**

Glomerulonephritis: Inflammation of the glomeruli, may be acute or chronic or may occur on its own or in conjunction with another disease.

Vasculitis/Polyarteritis Nodosa:	Inflammation in the blood vessels. May be due to infection, medical conditions, or an immunological response.
Malignancy (other than HCC):	Also referred to as cancer; a term for diseases in which abnormal cells divide without control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body. There are several main types of cancer. If the patient has been told by a physician that they have a malignancy or cancer, other than hepatocellular carcinoma (HCC) or liver cancer, check "Yes" and specify the type of malignancy/cancer in the space provided.

Section IV: Medication History

Current Medications: Check "Yes" or "No" to indicate if the patient is currently taking medication for one of the reasons listed. If yes, then check the appropriate category that corresponds to the reason the medication is being used. Note that investigator input may be required to determine the reason that a medication is taken since a given medication may fit into more than one of the categories listed, and it may be difficult to determine the reason a medication is taken.

Immunosuppressants: agents that suppress or prevent an immune response. Some common drugs in this class include but are not limited to corticosteroids, methotrexate, cyclosporine, azathioprine, Cellcept, Prograf and Arava.

Lipid-lowering agents: agents that aide in blocking the absorption of cholesterol or reducing cholesterol levels. Common agents in this class include but are not limited to antihyperlipedmic combinations (Caduet, Simcor), bile acid sequestrants (cholestyramine, colestipol), cholesterol absorption inhibitors (Zetia), fibric acid derivatives (fenofibrate,fenofibiric acid, gemfibrozil), and statins (lovastatin, rosuvastatin, simvastatin).

Anticoagulants: agents used to prevent the formation of blood clots. Common agents in this class include but are not limited to warfarin, heparins, platelet aggregation inhibitor (aspirin, Plavix, Tirofiban)

Anti-hypertensive agents: agents that are used to treat high blood pressure. Common agents in this class include but are not limited to diuretics (Furosemide, Spironolactone), beta-blockers (atenolol, metoprolol), ACE inhibitors (Benazepril, Captopril, Lisinopril, Ramipril), Angiotensin II receptors (Candesartan, Losartin, Valsartan), Direct-acting vasodilators (hydralazine), centrally acting agents (methyldopa, clonidine)

Anti-diabetic agents: agents that aide in the control of high or uncontrollable blood sugar for Type 1 or Type 2 diabetes or gestational diabetes. Common agents in this class include but are not limited to insulin (injection or oral), metformin, antidiabetic combinations (containing metformin and another drug), sulfonylureas (glimepiride, glyburide, and tolazamide), and incretin mimetics (Byetta).

Estrogen/birth control pills (containing estrogen): estrogen agents are typically used to relieve symptoms of menopause and other conditions that cause low levels of estrogen. Forms of estrogen include oral, patches, or topical. Birth control agents are used for the prevention of pregnancy and other medical conditions which include but not limited to regulation of menstrual cycles, endometriosis, and acne. Record only if the birth control agent contains estrogen. A common agent includes but is not limited to ethinyl estradiol and can be administered as a patch, an injection, or orally.

Other antivirals: any antiviral agents that are not indicated for treatment of hepatitis B. Types of agents include but are not limited to treatment for:

- hepatitis C: ribavirin
- herpes infections (e.g. herpes zoster, HSV): famciclovir, valacyclovir (Valtrex), and acyclovir
- CMV retinitis: ganciclovir, valganciclovir, and cidofovir
- Influenza: ramantadine, oseltamivir (Tamiflu), and zanamivir (Relenza)

If it is unclear that a specific medication is being taken for one of these reasons, check with the investigator or a source such as www.drugs.com for a group classification.

Herbal/natural medications: Check "Yes" or "No" to indicate if the patient is currently taking any herbs, herbals or natural medicines. Check "Unknown" if it is not known whether the patient is taking any herbs, herbal or natural medications.

Vitamins and minerals: Check "Yes" or "No" to indicate if the patient is currently taking any vitamins or minerals. Items are to be taken as a separate supplement and may be in pill or liquid form. If yes, check the appropriate type. Check "Unknown" if it is not known whether the patient is taking any vitamins or minerals.

Multi-vitamin: a supplement containing three or more vitamins or minerals but no herbs, hormones, or drugs. Common brand names include but are not limited to Centrum or One-a-Day. There are also multi-vitamins available as generic and store brands or prenatal vitamins.

Vitamin D: supplement specific to vitamin D and may be in combination with calcium. Do not include if part of a multi-vitamin supplement. Common vitamin D and calcium combinations include but are not limited to Os-Cal, Viactive, and Caltrate+D. Record vitamin D and calcium combinations as both Vitamin D and Calcium supplements.

Vitamin E: supplement specific to vitamin E. Do not include if part of a multi-vitamin supplement.

Folate: supplement specific to folate. May also be referred to as folic acid or vitamin B_9. Do not include if part of a multi-vitamin supplement.

Iron: supplement specific to iron. Do not include if part of a multi-vitamin supplement.

Calcium: supplement specific to calcium and may be in combination with Vitamin D. May be noted as calcium citrate, calcium carbonate, or calcium lactate. Do not include if part of a multi-vitamin supplement. Common vitamin D and calcium combinations include but are not limited to Os-Cal, Viactive, and Caltrate+D. Record vitamin D and calcium combinations as both Vitamin D and Calcium supplements.

Other: a vitamin or mineral other than those listed, and not part of a multi-vitamin supplement.

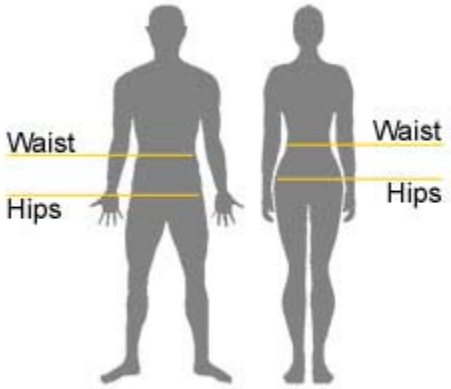
Section V: Physical Exam

Height: Record the patient's height at the time of the physical exam. Ask the patient to remove shoes prior to obtaining the measurement. Check "inches" or "cm" (centimeters) to indicate the unit of measure. If height was not measured then check "Not done". If for any reason (e.g. wheelchair-bound, equipment failure, etc.) a standing measurement is not obtained, record "Not done".

Weight: Record the patient's weight at the time of the physical exam. Check "lbs" (pounds) or "kg" (kilograms) to indicate the unit of measure. If weight was not measured then check "Not done".

Waist: Record the patient's waist circumference at the time of the physical exam. Do not complete a measurement in pregnant patients. Check "inches" or "cm" (centimeters) to indicate which unit of measure was used. If waist was not measured or the patient is pregnant then check "Not done".

To measure waist circumference, place a tape measure around the bare abdomen just above the hip bone (iliac crest). Be sure that the tape is snug (but does not compress skin) and that it is parallel to the floor. Ask the patient to relax, exhale, and then take the measurement.



Blood pressure: Record the patient's systolic and diastolic blood pressure in mmHg. Blood pressure should be obtained after the patient has been seated with both feet flat on the floor for at least 5 minutes. If blood pressure was not measured then check "Not done".

Current conditions: Check "Yes" or "No" for each item to indicate whether or not the patient currently has any of the following conditions, according to the study specific definitions provided below. If the assessment was not completed, check "Not Done".

Jaundice: Defined as the presence of bile pigment in the skin, mucous membrane, and sclera. There is a yellow discoloring of the skin, mucous membranes, and eyes.

Tender liver: Also known as tender hepatomegaly. The liver can be palpated and is tender.

Enlarged liver: Also known as hepatomegaly and is swelling of the liver beyond its normal size. An indication of enlarged liver is that the liver can be palpated below the costal margin (lower edge of ribs).

Enlarged spleen: Also known as splenomegaly and is swelling of the spleen beyond its normal size.

Peripheral edema: Defined as abnormal buildup of fluid in the ankles, feet, and legs.

Muscle wasting: Also known as muscle atrophy and is the loss and decrease in size of muscle tissue.

Spider angiomata: May also be recorded as spider angioma and is an abnormal collection of blood vessels near the surface of the skin. Appearance may have a red dot

in the center, reddish extensions that reach out from the center, and lesion disappears with pressure and reappears when pressure is released.
Palmar erythema: Defined as an inflammatory redness of the palms of the hands.

Pregnancy history: Check "Yes" or "No" to indicate if the patient has ever been pregnant. If the patient is male, check "N/A". If yes, complete the Pregnancy Questionnaire.

Current Pregnancy: Check "Yes" or "No" to indicate if the patient is currently pregnant. If the patient is male, check "N/A". If yes, record the month, day, and two digit year of the last menstrual period. If any part of the date is not known, record "Unk".

Section VI: Diagnostic Tests

Imaging: Check "Yes" if the patient has had liver related imaging tests such as MRI, CT, ultrasound, PET, or PET/CT completed within the past two years. If it is not known if an imaging test was performed within the past 2 years, check "Unknown".

If yes, complete the following information.

Date of most recent test: Provide the month and two digit year of the most recent test performed, regardless of the type of imaging. If the month is unknown, record "Unk" and provide the two digit year. If both month and year are unknown, record "Unk" for each field.

Tests performed: Check all liver related imaging tests (CT, MRI, ultrasound, PET, or PET/CT) that were performed in the past two years. If another type of imaging test was performed, check "Other" and specify the test in the space provided.

Report(s) available: Check "Yes" or "No" to indicate if one of more of the imaging reports from tests performed within the past 2 years are available.

If yes, use the combined results from the imaging tests to record "Yes", "No" or "Unknown" for the following findings: nodular liver, abnormal liver texture, enlarged spleen, ascites, venous collaterals, or changes indicative of steatosis. If a finding that is not included in the list is indicated on a report, check "Yes" to Other and specify the result in the space provided.

Liver biopsy: Check "Yes" if the patient had a liver biopsy performed in the past 2 years. If it is not known if a liver biopsy was performed in the past 2 years, check "Unknown".
HBV/HIV co-infected participants: check "Yes" if the patient has had a biopsy in the past 3 years. If it is not known if a liver biopsy was performed in the past 3 years, check "Unknown".

If yes, complete the Liver Biopsy form and complete the following information.

Date of most recent biopsy: Provide the month and two digit year of the most recent biopsy performed. If the month is unknown, record "Unk" and provide the two digit year. If both month and year are unknown, record "Unk" for each field.

Slides requested: Check "Yes" or "No" to indicate if slides (either unstained or stained) have been requested for the HBRN. Every effort should be made to obtain slides for the central reading. If possible, obtain slides that do not have to be returned to the local institution. If this is not possible, slides will be returned to the local institution after being read by the HBRN central pathologists.

Section VII: Treatment

Ever received HBV Treatment:	Check "Yes" or "No" to indicate if the patient has ever received treatment, either interferon or an oral antiviral agent for hepatitis B. *HBV/HIV co-infected participants*: check "N/A" and capture all HBV and HIV therapy on the AH Log If Yes, record the following information for each treatment the patient received: Antiviral therapy: Record the appropriate code for the treatment. If you know that the patient received interferon or an oral antiviral but do not know the specific agent, record -3 (Unknown) for the antiviral therapy code. *Note:* Tenofovir (TDF) = Tenofovir disoproxil fumarate Tenofovir (TAF) = tenofovir alafenamide fumarate Date started: Record the month, day, and two digit year that the treatment was started. If any piece of the date is not known, record "Unk". Date stopped: Record the month, day, and two digit year that the treatment was stopped. If any piece of the date is not known, record "Unk". If the patient is currently on this treatment, do not complete the date stopped fields and check "Currently on Therapy".

Section VIII: Risk Assessment

HBV diagnosis date:	Record the month and four digit year the patient was diagnosed with hepatitis B. If the month is unknown record "Unk" in that field and complete the year. If both the month and year are unknown, check "Unknown".
Transfusion:	Check "Yes", "No", or "Unknown" to indicate if the patient has ever had a blood transfusion. Procedures include but are not limited to blood transfusions or receipt of blood components or derivatives. If yes, record the month and year of the first transfusion. If the month is unknown record "Unk" in that field and complete the year. If both the month and year are unknown, check "Unknown".
Renal dialysis:	Check "Yes", "No", or "Unknown" to indicate if the patient has ever had renal dialysis. Alternative names for renal dialysis include artificial kidneys, hemodialysis, peritoneal dialysis, renal replacement therapy.
Hospital or health care setting:	Check "Yes", "No", or "Unknown" to indicate if the patient has ever worked in a hospital or other health care setting such as health centers/clinics, nursing homes, hospice/home care, psychiatric centers or dental centers, or an occupation where handling blood or blood products is routine. If yes, i. Check "Yes", "No", or "Unknown" to indicate if a needle stick ever occurred. ii. If a needle stick occurred, check "Yes", "No", or "Unknown" to indicate if the source patient was hepatitis B positive.
Injection drug use:	Check "Yes", "No", or "Unknown" to indicate if the patient has ever used intravenous/injection drugs not prescribed by a physician, which include but are not limited to heroin, cocaine, PCP, barbiturates, morphine, amphetamines, and methamphetamine.
Intra-nasal illicit	Check "Yes", "No", or "Unknown" to indicate if the patient has ever used any illicit drug use:drug by inhalation through the nose, which include but are not limited to cocaine, heroin, and amphetamines.

Household contact:	Check “Yes”, “No”, or “Unknown” to indicate if the patient has ever lived with someone who had hepatitis B at the time they were living together or shared household items such as razors, toothbrushes, or nail clippers with someone who had hepatitis B.
Body piercing:	Check “Yes”, “No”, or “Unknown” to indicate if the patient has ever had body piercing other than the ear. If yes, check “Yes”, “No”, or “Unknown”, to indicate if the patient had the piercing done by a professional.
Tattoo:	Check “Yes”, “No”, or “Unknown” to indicate if the patient has ever had a tattoo. If yes, check “Yes”, “No”, or “Unknown”, to indicate if the patient had the tattoo done by a professional.
Vertical transmission:	Check “Yes”, “No”, or “Unknown” to indicate if the patient’s birth mother was ever diagnosed with hepatitis B.

Section IX: Serologies and Autoantibodies

Record the most recent result obtained and the date of sample (month/year) for each test. If a test was never performed or a result is not available, check “Not done”. Patients not on treatment should have HBeAg and Anti-HBe tested at least once a year as standard of care. If HBV serologies were not performed within the last 2 years, the HBsAg, HBeAg, Anti-HBe should be tested as part of the baseline assessment.

HBsAg*:	Hepatitis B surface antigen. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation. If the test was not performed within the last 2 years the test should be performed as part of the baseline evaluation.
HBeAg*:	Hepatitis B e antigen. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation. If the test was not performed within the last 2 years the test should be performed as part of the baseline evaluation.
Anti-HBs*:	Antibody produced in response to Hepatitis B surface antigen. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation.
Anti-HBe*:	Antibody produced in response to Hepatitis B e antigen. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation. If the test was not performed within the last 2 years the test should be performed as part of the baseline evaluation.
Anti-HDV*:	Hepatitis delta antibody. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation.
Anti-HCV:	Hepatitis C antibody. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation.
Anti-HIV:	HIV antibody. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation. A positive test should be confirmed by Western blot.
Anti-HBc IgM:	Hepatitis B core IgM antibody. Record the most recent result at the time of the baseline evaluation or prior to the baseline evaluation. This test should be performed at the baseline visit if acute hepatitis B is suspected.
ANA:	Antinuclear antibody. Record the most recent result regardless of when the test was performed. (1) Record if the test result is positive or negative. (2) Record the titer. If a titer was not obtained, record “ND” in the titer field.

ASMA: Anti-smooth muscle antibody. Record the most recent result regardless of when the test was performed.
(1) Record if the test result is positive or negative.
(2) Record the titer. If a titer was not obtained, record "ND" in the titer field.

ALKM: Anti-liver/kidney microsomal antibody. Record the most recent result regardless of when the test was performed.
(1) Record if the test result is positive or negative.
(2) Record the titer. If a titer was not obtained, record "ND" in the titer field.

***** *HBV/HIV co-infected participants:* The specific HBV serologies noted above should be performed as part of the baseline evaluation if a test result within the prior 6 months is not available. Record the most recent result from a test performed at the time of the baseline evaluation or prior to the baseline evaluation.

Section X: Virology Tests

HBV genotype: Record the most recent result regardless of when the test was performed. If a result is not available or not know, check "Unknown".

HBV DNA level:
(1) Record the most recent DNA level completed at the time of the baseline evaluation or prior to the baseline evaluation. If a result is not available, check "Unknown".
(2) Record the month and two digit year the sample was obtained. If the month is unknown, record "Unk" and provide the two digit year. If both month and year are unknown, record "Unk" for both month and year.
(3) Check "IU/mL" or "copies/mL" to indicate the unit of measure.
(4) Record the lower limit of detection for the test. If the lower limit of detection is not available or unknown, record "Unk".

Section XI: Labs

Record the most recent result for each lab test. Tests are to be performed at the time of the baseline evaluation or within three months prior to the baseline evaluation. If the lab test was not completed at the time of the baseline evaluation or within the 3 months prior, check "Not done".

Date of sample: Record the date of sample (month/day/year) for the lab tests listed in this section.

Lab results:
(1) Record the result of the lab test.
(2) If a date of sample for a specific lab is not the same as the date of sample recorded at the top of the section, record the date (month/ day/year) the sample was obtained. If any part of the date is unknown, record "Unk".
(3) If the lab test was not completed or the result is not available, check "Not done".

ALT normal range: If ALT is completed, record the lower and upper reference range of normal.
If ALT result is ≥ 300 U/L (male) or ≥ 200 U/L (female) then complete a Follow-Up Event form.

AST normal range: If AST is completed, record the lower and upper reference range of normal.

Alkaline phosphatase normal range: If alkaline phosphatase is completed, record the lower and upper reference range of normal.

Section XII: Fasting Labs

The lab test results recorded in this section are to be fasting labs. The patient is to have had only water for the fasting period. A fasting period of 12 hours is optimal, with a minimum of 8 hours. If the patient has not met the fasting requirement at the baseline

visit, these laboratory tests should be completed at a subsequent baseline visit occurring before, or at the time of, the 12 week follow-up visit.

Fasting: Check "Yes" or "No" to indicate if the patient was fasting for this blood draw. If yes, record the length of the fasting period to the nearest hour.

Date of sample: Record the date of sample (month/day/year) for the lab tests listed in this section.

Lab results:
(1) Record the result of the lab test.
(2) If a date of sample for a specific lab is not the same as the date of sample recorded at the top of the section, record the date (month/ day/year) the sample was obtained. If any part of the date is unknown, record "Unk".
(3) If the lab test was not completed or the result is not available, check "Not done".

Section XIII: Fibroscan and Breath Test

Fibroscan consent: Check "Yes", "No", or "Not participating" to indicate if the patient provided informed consent to participate in the Fibroscan ancillary study.

Fibroscan test: Check "Yes" or "No" to indicate if a fibroscan was completed at the baseline visit.

If yes,
i. Record the date (month/day/year) the fibroscan was completed.
ii. Complete the Fibroscan Form.

Breath test consent: Check "Yes", "No", or "Not participating" to indicate if the patient provided informed consent to participate in the Breath Test ancillary study.

Breath test: Check "Yes" or "No" to indicate if a breath test was completed at the baseline visit.

If yes,
i. Record the date (month/day/year) the breath test was completed.
ii. Complete the Breath Test Form.

Section XIV: 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".

Section XV: Administrative

Baseline visit completion: Check "Yes" or "No" to indicate if all the components of the baseline visit (Baseline Evaluation Form, lab tests, fasting lab tests, serologies, virology tests, biospecimen collection, and patient questionnaires) were completed in one visit.

If no, record the last visit date (month/day/year) at which time all components of the baseline visit were complete.

All components of the baseline evaluation must be completed between the baseline evaluation visit and the 12 Week follow-up visit. Some components of the baseline evaluation must be completed at the initial baseline visit. Refer to the Cohort Study protocol for the list of baseline evaluation components that may be completed in the time period between the initial baseline visit and the Week 12 follow-up visit.

Language: Check “Yes” or “No” to indicate if the patient speaks English, and will complete the English version of the self-assessment questionnaires. If no, check “Spanish”, “Chinese”, “Korean”, or “Vietnamese” to specify the language used to complete the self-assessments. If the language is not listed, check “Other” and specify the language in the space provided.