NAFLD Database 2

AD – Alcohol Use Disorders Identification Test (AUDIT)

Purpose: To screen for current heavy drinking and/or active alcohol abuse or dependence.
When: Screening visit t0.
Administered by: Self-administered. Clinical Coordinator must be available at visits to answer questions and review completed forms.
Respondent: Patient age 12 or older.
Instructions: Flash Card #9, Drink Equivalents, may be used with this form. The Clinical Coordinator should complete section A below and write the patient ID on pages 2-3. The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator then should complete section B below.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: **t 0** _____ _____

6. Form & revision: **a d 1**

7. Study: NAFLD Database 2 6

B. Administrative information

(To be completed by Clinical Coordinator after survey is completed.)

8. How was the questionnaire completed:

Self-administered by patient (1)
Interview with translator (2)

9. Clinical Coordinator
a. PIN: _____ _____ _____
b. Signature:

_____

10. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

AD – Alcohol Use Disorders Identification Test (AUDIT)

Instructions: This survey asks for your views about your alcohol use. Please check one for each question below *(items 1-10 are for clinical center use only)* .

11. How often do you have a drink containing alcohol?

Never	Monthly or less	Two to four times a month	Two to three times a week	Four or more times a week
(0) → **21.**	(1)	(2)	(3)	(4)

12. How many drinks containing alcohol do you have on a typical day when you are drinking?

1 or 2	3 or 4	5 or 6	7 to 9	10 or more
(0)	(1)	(2)	(3)	(4)

13. How often do you have six or more drinks on one occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

14. How often during the last year have you found that you were not able to stop drinking once you had started?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

15. How often during the last year have you failed to do what was normally expected from you because of drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

16. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

17. How often during the last year have you had a feeling of guilt or remorse after drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

18. How often during the last year have you been unable to remember what happened the night before because you had been drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(1)	(2)	(3)	(4)

19. Have you or someone else been injured as a result of your drinking?

No	Yes, but not in the last year	Yes, during the last year
(0)	(1)	(2)

20. Has a relative or friend, or a doctor or other health worker been concerned about your drinking or suggested you cut down?

No	Yes, but not in the last year	Yes, during the last year
(0)	(1)	(2)

21. Today's date:

_____

Thank you for completing this questionnaire.

NAFLD Database 2

BG - Baseline History

Purpose: To collect baseline history information about the patient.
When: Visit t0.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient or patient's parent.
Instructions: Collect information by interview and chart review. If C is checked for an item, and the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database 2 Study. If EXC is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database 2 Study. The form should not be keyed to the data system; but the form should be set aside with forms for other patients who started screening, but were found to be ineligible.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

6. Form & revision: b g 1

7. Study: NAFLD Database 2 6

B. Family history

8. Do any of the patient's first degree relatives (parent, brother, sister, child) have liver disease:

( ) Yes (1) ( ) No (2)

10.

9. If yes, characterize the liver disease(s) *(check all that apply)*

a. Alcohol related liver disease: (1)
b. Viral hepatitis: (1)
c. Alpha-1 antitrypsin deficiency: (1)
d. Wilson's disease: (1)
e. Glycogen storage disease: (1)
f. Iron overload: (1)
g. Fatty liver disease *(NAFLD, NASH):* (1)
h. Type of liver disease unknown: (1)
i. Other *(specify):* (1)

_____
specify

10. Do any of the patient's first degree relatives (parent, brother, sister, child) have cirrhosis:

( ) Yes (1) ( ) No (2)

12.

11. If yes, is the cause of the cirrhosis NASH-related or unknown (cryptogenic):

( ) Yes (1) ( ) No (2)

12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2):

Yes (1)
No (2)
Don't know (3)

13. Do any of the patient's first degree relatives (parent, brother, sister, child) have obesity:

Yes (1)
No (2)
Don't know (3)

14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat:

Yes (1)
No (2)
Don't know (3)

15. Do any of the patient's first degree relatives (parent, brother, sister, child) have a problem with cholesterol or blood fat:

Yes (1)
No (2)
Don't know (3)

C. NAFLD history

16. Date patient was first diagnosed with fatty liver disease or NASH-related cirrhosis:

____ ____–____ ____ ____–____ ____
day mon year

17. What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis *(check all that apply)*

a. Symptoms for liver disease: (1)
b. Result of being evaluated for another illness: (1)
c. During a routine or insurance physical examination: (1)
d. Blood donation: (1)
e. Other *(specify):* (1)

_____
specify

18. What procedures/tests supported this first diagnosis *(check all that apply)*

a. Liver biopsy: (1)
b. Imaging studies *(Ultrasound, CT, MRI):* (1)
c. Elevated aminotransferases: (1)
d. Other *(specify):* (1)

_____
specify

19. Does the patient have a liver biopsy done no more than 90 days prior to registration in the Database 2 Study that you want evaluated for the Database 2 Study *(complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy):*

Yes (*1) No (2)
21.

**Blood drawn for specimen collection must be within 90 days of the biopsy.*

20. Date of liver biopsy no more than 90 days prior to registration in Database 2 Study that you want evaluated:

____ ____–____ ____ ____–____ ____
day mon year

21. Will the patient have a biopsy during screening:

Yes (*1) No (2)

**Complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy. Blood draw for banking should be done prior to the biopsy or 4 days after the biopsy.*

22. Has the patient had a liver imaging study in the past 6 months:

Yes (*1) No (2)

**Complete the Liver Imaging Studies Report (IR) form.*

D. Weight history

23. What was the patient's birthweight:

____ ____–____ ____
lbs oz

24. *Review flashcard 11.* Which (picture) best describes your weight pattern over the past 5 years *(check only one):*

Up and down, up and down (1)
Up gradually (2)
Up sharply *(gained a lot in a brief interval)* (3)
Down gradually (4)
Down sharply *(lost a lot in a brief interval)* (5)
No or minimal change (6)

25. What is the patient's current weight *(ask the patient for his/her weight):*

____ ____ ____
lbs

26. What is the most the patient has ever weighed:

____ ____ ____
lbs

27. At what age did the patient weigh the most:

____ ____
age in years

28. Is the patient age 18 or older:

Yes (1) No (2)
31.

29. What is the least the patient has ever weighed since age 18:

____ ____ ____
lbs

30. At what age did the patient weigh the least since age 18:

____ ____
age in years

31. Does the patient weigh more than he/she did one year ago:

Yes (1) No (2)
33.

32. How much more does the patient weigh now compared to one year ago:

____ ____ ____
lbs

33. Does the patient weigh less than he/she did one year ago:

Yes (1) No (2)
35.

34. How much less does the patient weigh now compared to one year ago:

____ ____ ____
lbs

35. Did the patient try to lose or gain weight:

Yes (1) No (2)
37.

36. Which did the patient try to do *(check only one):*

Gain weight (1)
Lose weight (2)

E. Tobacco cigarette smoking history *(interview with patient; not interview with parent, not by chart review)*

37. Is the patient age 12 or older:

Yes (1) No (2)
43.

38. Have you ever smoked tobacco cigarettes:

Never (1)
43.
In the past but not anymore (2)
Currently smokes cigarettes (3)

39. Did you smoke cigarettes regularly *("No" means less than 20 packs of cigarettes in a lifetime or less than 1 cigarette a day for one year):*

Yes (1) No (2)
43.

40. How old were you when you first started regular cigarette smoking:

____ ____
years

41. How old were you when you (last) stopped smoking cigarettes *(code as "n" if the patient didn't stop smoking):*

____ ____
years

42. On the average of the entire time that you smoked cigarettes, how many cigarettes did you smoke per day:

____ ____ ____
cigarettes/day

F. Menstrual history

43. Is the patient female:

(Yes 1) (No 2)

49. ____

44. Has menarche occurred:

(Yes 1) (No 2)

49. ____

45. If yes, what was the patient's age at menarche:

____ ____
age in years

46. Characterize the menstrual history in the past 5 years *(check only one):*

Regular periods (1)
Irregular periods (2)
Rare periods (3)
No periods (4)

47. Is patient post-menopausal:

(Yes 1) (No 2)

49. ____

48. What was the patient's age at menopause:

____ ____
age in years

G. Medical history *(C means Caution; condition is exclusionary if study physician agrees with diagnosis)*

49. Has the patient ever been diagnosed with and treated for any of the following *(check all that apply; source of information can be interview and/or chart review)*

a. Diabetes type 1: (1)

b. Diabetes type 2: (1)

c. Gestational diabetes *(diabetes of pregnancy):* (1)

d. Hepatitis B: (1) C ____

e. Hepatitis C: (1) C ____

f. Autoimmune hepatitis: (1)

g. Autoimmune cholestatic liver disorder (PBC or PSC): (1) C ____

h. Wilson's disease: (1) C ____

i. Alpha-1-antitrypsin (A1AT) deficiency: (1) C ____

j. Glycogen storage disease: (1) C ____

k. Iron overload: (1) C ____

l. Polycystic liver disease: (1)

m. Drug induced liver disease: (1)

n. Gilbert's syndrome: (1)

o. Esophageal or gastric varices on endoscopy: (1)

p. Bleeding from varices: (1)

q. Other gastrointestinal bleeding: (1)

r. Ascites: (1)

s. Edema: (1)

t. Hepatic encephalopathy: (1)

u. Portal hypertension: (1)

v. Hepatorenal syndrome: (1)

w. Hepatopulmonary syndrome: (1)

x. Short bowel syndrome: (1) C ____

y. Hemophilia *(bleeding disorder):* (1) C ____

z. HIV positive: (1) C ____

aa. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: (1)

ab. Endocrine disease *(hormonal abnormality):* (1)

ac. Hepatocellular carcinoma: (1) C ____

ad. Other malignancy *(cancer):* (1)

ae. Peripheral neuropathy: (1)

af. Seizure disorder or epilepsy: (1)

ag. Drug allergies: (1)

ah. Hypothyroidism: (1)

ai. Hypertension: (1)

aj. Cerebrovascular disease: (1)

ak. Dysbetalipoproteinemia: (1)

C

al. Chronic cholestasis: (1)

am. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

an. Pancreatitis: (1)

ao. Cholelithiasis: (1)

ap. Coronary artery disease: (1)

aq. Elevated uric acid such as gout: (1)

ar. Kidney disease: (1)

as. Polycystic ovary syndrome: (1)

at. Sleep apnea *(not breathing during sleep):* (1)

au. Dermatologic disorders: (1)

av. Myopathy: (1)

aw. Myositis: (1)

ax. Major depression: (1)

ay. Schizophrenia: (1)

az. Bipolar disorder: (1)

ba. Obsessive compulsive disorder: (1)

bb. Severe anxiety or personality disorder: (1)

bc. None of the above: (1)

50. Has the patient ever had surgery for any of the following *(check all that apply)*

a. Stapling or banding of the stomach: (1)

C

b. Jejunoileal *(or other intestinal)* bypass prior to the diagnosis of NAFLD: (1)

C

c. Biliopancreatic diversion: (1)

C

d. Other GI or bariatric surgery *(specify):* (1)

_____

e. None of the above: (1)

51. Organ, limb, or bone marrow transplant

a. Has the patient ever received a liver transplant:

Yes (1) No (2)

b. Has the patient ever received any other organ, limb, or bone marrow transplant:

Yes (1) No (2)

52. Has the patient received total parenteral nutrition (TPN) for more than 1 month within 6 months prior to liver biopsy:

Yes (1) No (2)

F.Hg

53. Is the patient currently undergoing evaluation for bariatric surgery:

Yes (1) No (2)

54. Does the patient have symptoms suggestive of sleep apnea *(snoring, observed periods of apnea, disruptive sleep disturbances):*

Yes (1) No (2)

H. Medication use

55. Has the patient used any antidiabetic medications in the past 3 months:

(Yes 1) (No 2)

56.

(If yes, check all that apply):

a. Acarbose (Precose): (1)

b. Acetohexamide (Dymelor): (1)

c. Chlorpropamide (Diabinese): (1)

d. Glimepiride (Amaryl): (1)

e. Glipizide (Glucotrol, Glucotrol XL): (1)

f. Glyburide (Micronase, DiaBeta, Glynase): (1)

g. Insulin: (1)

h. Metformin (Glucophage, Glucophage XR): (1)

i. Miglitol (Glycet): (1)

j. Nateglinide (Starlix): (1)

k. Pioglitazone (Actos): (1)

l. Repaglinide (Prandin): (1)

m. Rosiglitazone (Avandia): (1)

n. Tolazamide (Tolinase): (1)

o. Tolbutamide (Orinase): (1)

p. Other, *(specify):* (1)

_____

56. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 3 months:

(Yes 1) (No 2)

57.

(If yes, check all that apply):

a. Chlordiazepoxide (Librium): (1)

b. Clorazepate dipotassium (Tranxene): (1)

c. Diazepam (Valium): (1)

d. Disulfiram (Antabuse): (1)

e. Hydroxyzine pamoate (Vistaril): (1)

f. Naltrexone hydrochloride (Revia): (1)

g. Other, *(specify):* (1)

_____

57. Has the patient taken any antihyperlipidemic medications in the past 3 months:

(Yes 1) (No 2)

58.

(If yes, check all that apply):

a. Atorvastatin (Lipitor): (1)

b. Colestipol hydrochloride (Colestid): (1)

c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (1)

d. Gemfibrozil (Gen-Fibro, Lopid): (1)

e. Fenofibrate (Tricor): (1)

f. Fluvastatin sodium (Lescol): (1)

g. Lovastatin (Mevacor): (1)

h. Nicotinic acid (Niaspan): (1)

i. Pravastatin sodium (Pravachol): (1)

j. Rosuvastatin (Crestor): (1)

k. Simvastatin (Zocor): (1)

l. Other, *(specify):* (1)

_____

58. Has the patient taken any antiobesity medications in the past 3 months:

(Yes 1) (No 2)

59.

(If yes, check all that apply):

a. Dexfenfluramine hydrochloride (Redux): (1)

b. Fenfluramine hydrochloride (Pondimin): (1)

c. Methamphetamine hydrochloride (Desoxyn, Gradumet): (1)

d. Orlistat (Xenical): (1)

e. Phendimetrazine tartrate (Adipost, Bontril): (1)

f. Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine): (1)

g. Sibutramine hydrochloride monohydrate (Meridia): (1)

h. Other, *(specify):* (1)

_____

59. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 3 months:

Yes (1) No (2)

60.

(If yes, check all that apply):

a. Acetaminophen (Tylenol): (1)

b. Aspirin - 325 mg: (1)

c. Aspirin - 81 mg: (1)

d. Celecoxib (Celebrex): (1)

e. Ibuprofen (Advil, Motrin): (1)

f. Indomethacin (Indocin): (1)

g. Naproxen (Aleve, Naprosyn): (1)

h. Rofecoxib (Vioxx): (1)

i. Other, *(specify):* (1)

_____

j. Other, *(specify):* (1)

_____

60. Has the patient taken any strong opiates containing acetaminophen medication in the past 3 months:

Yes (1) No (2)

61.

(If yes, check all that apply):

a. Darvocet: (1)

b. Esgic - Plus: (1)

c. Fioricet: (1)

d. Lorcet: (1)

e. Lortab: (1)

f. Norco: (1)

g. Percocet: (1)

h. Talacen: (1)

i. Tylenol #3: (1)

j. Tylenol #4: (1)

k. Tylox: (1)

l. Vicodin: (1)

m. Wygesic: (1)

n. Other, *(specify):* (1)

_____

61. Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications in the past 3 months:

Yes (1) No (2)

62.

(If yes, check all that apply):

a. Cimetidine (Tagamet): (1)

b. Esomeprazole magnesium (Nexium): (1)

c. Famotidine (Pepcid): (1)

d. Lansoprazole (Prevacid): (1)

e. Nizatidine (Axid): (1)

f. Omeprazole (Prilosec): (1)

g. Ranitidine (Zantac): (1)

h. Ranitidine bismuth citrate (Tritec): (1)

i. Antacids, *(specify):* (1)

_____

j. Other, *(specify):* (1)

_____

62. Has the patient taken any anticoagulant/antiplatelet medications in the past 3 months:

Yes (1) No (2)

63.

(If yes, check all that apply):

a. Clopidogrel (Plavix): (1)

b. Dipyridamole: (1)

c. Heparin: (1)

d. Ticlopide (Ticlid): (1)

e. Warfarin (Coumadin): (1)

f. Other, *(specify):* (1)

_____

63. Has the patient taken any systemic corticosteroids in the past 3 months:

( ) Yes (1) ( ) No (2)

64.

(If yes, check all that apply):

a. Betamethasone sodium (Celestone): ( ) (1)

b. Cortisol: ( ) (1)

c. Cortisone: ( ) (1)

d. Dexamethasone (Decadron): ( ) (1)

e. Hydrocortisone (Hydrocortone): ( ) (1)

f. Methylprednisolone (Solu-Medrol): ( ) (1)

g. Prednisolone (Prelone): ( ) (1)

h. Prednisone: ( ) (1)

i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort): ( ) (1)

j. Other, *(specify):* ( ) (1)

_____

64. Has the patient taken any cardiovascular/antihypertensive medications in the past 3 months:

( ) Yes (1) ( ) No (2)

65.

(If yes, check all that apply):

a. Amiodarone (Pacerone): ( ) (1)

b. Amlodipine besylate (Norvasc): ( ) (1)

c. Atenolol (Tenormin): ( ) (1)

d. Benazepril (Lotensin): ( ) (1)

e. Captopril (Capoten): ( ) (1)

f. Clonidine (Catapres): ( ) (1)

g. Digoxin (Lanoxin): ( ) (1)

h. Diltiazem (Cardizem): ( ) (1)

i. Doxazosin (Cardura): ( ) (1)

j. Enalapril (Vasotec): ( ) (1)

k. Felodipine (Plendil): ( ) (1)

l. Furosemide (Lasix): ( ) (1)

m. Hydrochlorothiazide (Esidrix, HydroDIURIL): ( ) (1)

n. Hydrochlorothiazide + triamterene (Dyazide): ( ) (1)

o. Lisinopril (Prinivil, Zestril): ( ) (1)

p. Losartan potassium (Cozaar): ( ) (1)

q. Losartan potassium with hydrochlorothiazide (Hyzaar): ( ) (1)

r. Metoprolol (Lopressor): ( ) (1)

s. Nifedipine (Adalat, Procardia): ( ) (1)

t. Perhexiline maleate: ( ) (1)

u. Propranolol (Inderal): ( ) (1)

v. Quinapril (Accupril): ( ) (1)

w. Terazosin (Hytrin): ( ) (1)

x. Timolol maleate (Blocadren): ( ) (1)

y. Valsartan (Diovan): ( ) (1)

z. Verapamil (Calan): ( ) (1)

aa. Other, *(specify):* ( ) (1)

_____

ab. Other, *(specify):* ( ) (1)

_____

65. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 3 months:

Yes (1) No (2)

66.

(If yes, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

f. Fluoxymesterone (Android-F, Halotestin): (1)

g. Levonorgestrel (Norplant): (1)

h. Medroxyprogesterone (Cycrin, Provera): (1)

i. Megestrol (Megace): (1)

j. Methyltestosterone (Android): (1)

k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin): (1)

l. Norethindrone (Micronor): (1)

m. Norgestrel (Ovrette): (1)

n. Oral contraceptives: (1)

o. Oxandrolone (Oxandrin): (1)

p. Oxymetholone (Anadrol): (1)

q. Progesterone (Prometrium): (1)

r. Raloxifene (Evista): (1)

s. Tamoxifen (Nolvadex): (1)

t. Other, *(specify):* (1)

_____

u. Other, *(specify):* (1)

_____

66. Has the patient taken any allergy or asthma medications in the past 3 months:

Yes (1) No (2)

67.

(If yes, check all that apply):

a. Beclomethasone dipropionate (Beclovent, Vanceril): (1)

b. Budesonide (Pulmicort, Rhinocort): (1)

c. Fluticasone propionate (Flonase, Flovent): (1)

d. Loratadine (Claritin): (1)

e. Mometasone furoate (Nasonex): (1)

f. Triamcinolone acetonide (Azmacort, Nasacort): (1)

g. Other, *(specify):* (1)

_____

h. Other, *(specify):* (1)

_____

67. Has the patient taken a multivitamin regularly in the past 3 months:

Yes (1) No (2)

68. Has the patient taken vitamins other than multivitamins in the past 3 months:

Yes (1) No (2)

70.

69. Which vitamins has the patient taken *(check all that apply):*

a. Vitamin B (any type): (1)

b. Vitamin C: (1)

c. Vitamin D: (1)

d. Vitamin E: (1)

e. Other, *(specify):* (1)

_____

70. Has the patient taken any supplements in the past 3 months:

Yes (1) No (2)

71.

(If yes, check all that apply):

a. Alpha-lipoic acid: (1)

b. Alpha-tocopherol: (1)

c. Beta-carotene: (1)

d. Betaine (Cystadane): (1)

e. Calcium (any form): (1)

f. Carnitine (any form): (1)

g. Chondroitin (any form): (1)

h. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): (1)

i. Cod liver oil: (1)

j. Coenzyme Q: (1)

k. Dichloroacetate: (1)

l. Echinacea: (1)

m. Fish oil (any form): (1)

n. Flax seed oil: (1)

o. Garlic: (1)

p. Ginkgo biloba: (1)

q. Glucosamine (any form): (1)

r. Lecithin: (1)

s. Magnesium: (1)

t. Milk thistle: (1)

u. N-acetyl-cysteine: (1)

v. Potassium (any form): (1)

w. S-adenylmethionine (SAM-e): (1)

x. Saw palmetto: (1)

y. Selenium: (1)

z. St. John's Wort: (1)

aa. Taurine: (1)

ab. Zinc picolinate: (1)

ac. Other, *(specify):* (1)

_____

ad. Other, *(specify):* (1)

_____

71. Has patient taken any of the following medications or other supplements/medications in the past 3 months:

Yes (1) No (2)

72.

(If yes, record all other supplements/medications):

a. Demeclocycline (Declomycin): (1)

b. Divalproex (Depakote): (1)

c. Doxycycline (Monodox): (1)

d. Isotretinoin (Accutane): (1)

e. Levothyroxine (Levoxyl, Synthroid): (1)

f. Liothyronine (Cytomel): (1)

g. Methotrexate (Rheumatrex): (1)

h. Minocycline (Dynacin, Minocin): (1)

i. Oxytetracycline (Terramycin): (1)

j. Penicillamine (Cuprimine, Depen): (1)

k. Tetracycline (Achromycin): (1)

l. Trientine hydrochloride (Syprine): (1)

m. Ursodeoxycholic acid (Actigall, Urso, Ursodiol): (1)

n. Valproate sodium (Depacon): (1)

o. Valproic acid (Depakene): (1)

p. Other, *(specify):* (1)

_____

q. Other, *(specify):* (1)

_____

r. Other, *(specify):* (1)

_____

I. Administrative information

72. Study Physician PIN: ____ ____ ____

73. Study Physician signature:

_____

74. Clinical Coordinator PIN: ____ ____ ____

75. Clinical Coordinator signature:

_____

76. Date form reviewed:):

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

BG - Baseline History

Purpose: To collect baseline history information about the patient.
When: Visit t0.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient or patient's parent.
Instructions: Collect information by interview and chart review. If ⚠C is checked for an item, and the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database 2 Study. If EXC is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database 2 Study. The form should not be keyed to the data system; but the form should be set aside with forms for other patients who started screening, but were found to be ineligible.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

6. Form & revision: b g 2

7. Study: NAFLD Database 2 6

B. Family history

8. Do/did any of the patient's first degree relatives (parent, brother, sister, child) have liver disease:

(Yes 1) (No 2)

10.

a. Did any of the patient's first degree relatives die from liver disease:

(Yes 1) (No 2)

9. If yes, characterize the liver disease(s) *(check all that apply)*

a. Alcohol related liver disease: (1)
b. Viral hepatitis: (1)
c. Alpha-1 antitrypsin deficiency: (1)
d. Wilson's disease: (1)
e. Glycogen storage disease: (1)
f. Iron overload: (1)
g. Fatty liver disease *(NAFLD, NASH):* (1)
h. Type of liver disease unknown: (1)
i. Other *(specify):* (1)

_____
specify

10. Do/did any of the patient's first degree relatives (parent, brother, sister, child) have cirrhosis:

(Yes 1) (No 2)

12.

11. If yes, is the cause of the cirrhosis NASH-related or unknown (cryptogenic):

(Yes 1) (No 2)

12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2):

Yes (1)
No (2)
Don't know (3)

13. Do any of the patient's first degree relatives (parent, brother, sister, child) have obesity:

Yes (1)
No (2)
Don't know (3)

14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat:

Yes (1)
No (2)
Don't know (3)

15. Do any of the patient's first degree relatives (parent, brother, sister, child) have a problem with cholesterol or blood fat:

Yes (1)
No (2)
Don't know (3)

C. NAFLD history

16. Date patient was first diagnosed with fatty liver disease or NASH-related cirrhosis:

____ ____–____ ____ ____–____ ____
day mon year

17. What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis *(check all that apply)*

a. Symptoms for liver disease: (1)
b. Result of being evaluated for another illness: (1)
c. During a routine or insurance physical examination: (1)
d. Blood donation: (1)
e. Other *(specify):* (1)

_____
specify

18. What procedures/tests supported this first diagnosis *(check all that apply)*

a. Liver biopsy: (1)
b. Imaging studies *(Ultrasound, CT, MRI):* (1)
c. Elevated aminotransferases: (1)
d. Other *(specify):* (1)

_____
specify

19. Does the patient have a liver biopsy done no more than 90 days prior to registration in the Database 2 Study that you want evaluated for the Database 2 Study *(complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy):*

Yes (*1) No (2)
21.

**Blood drawn for specimen collection must be within 90 days of the biopsy.*

20. Date of liver biopsy no more than 90 days prior to registration in Database 2 Study that you want evaluated:

____ ____–____ ____ ____–____ ____
day mon year

21. Will the patient have a biopsy during screening:

Yes (*1) No (2)

**Complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy. Blood draw for banking should be done prior to the biopsy or 4 days after the biopsy.*

22. Has the patient had a liver imaging study in the past 6 months:

Yes (*1) No (2)

**Complete the Liver Imaging Studies Report (IR) form.*

D. Weight history

23. What was the patient's birthweight:

____ ____–____ ____
lbs oz

24. *Review flashcard 11.* Which (picture) best describes your weight pattern over the past 5 years *(check only one):*

Up and down, up and down (1)
Up gradually (2)
Up sharply *(gained a lot in a brief interval)* (3)
Down gradually (4)
Down sharply *(lost a lot in a brief interval)* (5)
No or minimal change (6)

25. What is the patient's current weight *(ask the patient for his/her weight):*

____ ____ ____
lbs

26. What is the most the patient has ever weighed:

____ ____ ____
lbs

27. At what age did the patient weigh the most:

____ ____
age in years

28. Is the patient age 18 or older:

Yes (1) No (2)
31.

29. What is the least the patient has ever weighed since age 18:

____ ____ ____
lbs

30. At what age did the patient weigh the least since age 18:

____ ____
age in years

31. Does the patient weigh more than he/she did one year ago:

Yes (1) No (2)
33.

32. How much more does the patient weigh now compared to one year ago:

____ ____ ____
lbs

33. Does the patient weigh less than he/she did one year ago:

Yes (1) No (2)
35.

34. How much less does the patient weigh now compared to one year ago:

____ ____ ____
lbs

35. Did the patient try to lose or gain weight:

Yes (1) No (2)
37.

36. Which did the patient try to do *(check only one):*

Gain weight (1)
Lose weight (2)

E. Tobacco cigarette smoking history *(interview with patient; not interview with parent, not by chart review)*

37. Is the patient age 12 or older:

Yes (1) No (2)
43.

38. Have you ever smoked tobacco cigarettes:

Never (1)
43.
In the past but not anymore (2)
Currently smokes cigarettes (3)

39. Did you smoke cigarettes regularly *("No" means less than 20 packs of cigarettes in a lifetime or less than 1 cigarette a day for one year):*

Yes (1) No (2)
43.

40. How old were you when you first started regular cigarette smoking:

____ ____
years

41. How old were you when you (last) stopped smoking cigarettes *(code as "n" if the patient didn't stop smoking):*

____ ____
years

42. On the average of the entire time that you smoked cigarettes, how many cigarettes did you smoke per day:

____ ____ ____
cigarettes/day

F. Menstrual history

43. Is the patient female:

(Yes 1) (No 2)

49.

44. Has menarche occurred:

(Yes 1) (No 2)

49.

45. If yes, what was the patient's age at menarche:

____ ____
age in years

46. Characterize the menstrual history in the past 5 years *(check only one):*

Regular periods (1)
Irregular periods (2)
Rare periods (3)
No periods (4)

47. Is patient post-menopausal:

(Yes 1) (No 2)

49.

48. What was the patient's age at menopause:

____ ____
age in years

G. Medical history *(C means Caution; condition is exclusionary if study physician agrees with diagnosis)*

49. Has the patient ever been diagnosed with and treated for any of the following *(check all that apply; source of information can be interview and/or chart review)*

a. Diabetes type 1: (1)

b. Diabetes type 2: (1)

c. Gestational diabetes *(diabetes of pregnancy):* (1)

d. Hepatitis B: (1) C

e. Hepatitis C: (1) C

f. Autoimmune hepatitis: (1)

g. Autoimmune cholestatic liver disorder (PBC or PSC): (1) C

h. Wilson's disease: (1) C

i. Alpha-1-antitrypsin (A1AT) deficiency: (1) C

j. Glycogen storage disease: (1) C

k. Iron overload: (1) C

l. Polycystic liver disease: (1)

m. Drug induced liver disease: (1)

n. Gilbert's syndrome: (1)

o. Esophageal or gastric varices on endoscopy: (1)

p. Bleeding from varices: (1)

q. Other gastrointestinal bleeding: (1)

r. Ascites: (1)

s. Edema: (1)

t. Hepatic encephalopathy: (1)

u. Portal hypertension: (1)

v. Hepatorenal syndrome: (1)

w. Hepatopulmonary syndrome: (1)

x. Short bowel syndrome: (1) C

y. Hemophilia *(bleeding disorder):* (1) C

z. HIV positive: (1) C

aa. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: (1)

ab. Endocrine disease *(hormonal abnormality):* (1)

ac. Hepatocellular carcinoma: (1) C

ad. Other malignancy *(cancer):* (1)

ae. Peripheral neuropathy: (1)

af. Seizure disorder or epilepsy: (1)

ag. Drug allergies: (1)

ah. Hypothyroidism: (1)

ai. Hypertension: (1)

aj. Cerebrovascular disease: (1)

ak. Dysbetalipoproteinemia: (1)

C

al. Chronic cholestasis: (1)

am. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

an. Pancreatitis: (1)

ao. Cholelithiasis: (1)

ap. Coronary artery disease: (1)

aq. Elevated uric acid such as gout: (1)

ar. Kidney disease: (1)

as. Polycystic ovary syndrome: (1)

at. Sleep apnea *(not breathing during sleep):* (1)

au. Dermatologic disorders: (1)

av. Myopathy: (1)

aw. Myositis: (1)

ax. Major depression: (1)

ay. Schizophrenia: (1)

az. Bipolar disorder: (1)

ba. Obsessive compulsive disorder: (1)

bb. Severe anxiety or personality disorder: (1)

bc. None of the above: (1)

50. Has the patient ever had surgery for any of the following *(check all that apply)*

a. Stapling or banding of the stomach: (1)

C

b. Jejunoileal *(or other intestinal)* bypass prior to the diagnosis of NAFLD: (1)

C

c. Biliopancreatic diversion: (1)

C

d. Other GI or bariatric surgery *(specify):* (1)

_____

e. None of the above: (1)

51. Organ, limb, or bone marrow transplant

a. Has the patient ever received a liver transplant:

Yes (1) No (2)

b. Has the patient ever received any other organ, limb, or bone marrow transplant:

Yes (1) No (2)

52. Has the patient received total parenteral nutrition (TPN) for more than 1 month within 6 months prior to liver biopsy:

Yes (1) No (2)

FHg

53. Is the patient currently undergoing evaluation for bariatric surgery:

Yes (1) No (2)

54. Does the patient have symptoms suggestive of sleep apnea *(snoring, observed periods of apnea, disruptive sleep disturbances):*

Yes (1) No (2)

H. Medication use

55. Has the patient used any antidiabetic medications in the past 3 months:

(Yes 1) (No 2)

56.

(If yes, check all that apply):

a. Acarbose (Precose): (1)

b. Acetohexamide (Dymelor): (1)

c. Chlorpropamide (Diabinese): (1)

d. Glimepiride (Amaryl): (1)

e. Glipizide (Glucotrol, Glucotrol XL): (1)

f. Glyburide (Micronase, DiaBeta, Glynase): (1)

g. Insulin: (1)

h. Metformin (Glucophage, Glucophage XR): (1)

i. Miglitol (Glycet): (1)

j. Nateglinide (Starlix): (1)

k. Pioglitazone (Actos): (1)

l. Repaglinide (Prandin): (1)

m. Rosiglitazone (Avandia): (1)

n. Tolazamide (Tolinase): (1)

o. Tolbutamide (Orinase): (1)

p. Other, *(specify):* (1)

_____

56. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 3 months:

(Yes 1) (No 2)

57.

(If yes, check all that apply):

a. Chlordiazepoxide (Librium): (1)

b. Clorazepate dipotassium (Tranxene): (1)

c. Diazepam (Valium): (1)

d. Disulfiram (Antabuse): (1)

e. Hydroxyzine pamoate (Vistaril): (1)

f. Naltrexone hydrochloride (Revia): (1)

g. Other, *(specify):* (1)

_____

57. Has the patient taken any antihyperlipidemic medications in the past 3 months:

(Yes 1) (No 2)

58.

(If yes, check all that apply):

a. Atorvastatin (Lipitor): (1)

b. Colestipol hydrochloride (Colestid): (1)

c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (1)

d. Gemfibrozil (Gen-Fibro, Lopid): (1)

e. Fenofibrate (Tricor): (1)

f. Fluvastatin sodium (Lescol): (1)

g. Lovastatin (Mevacor): (1)

h. Nicotinic acid (Niaspan): (1)

i. Pravastatin sodium (Pravachol): (1)

j. Rosuvastatin (Crestor): (1)

k. Simvastatin (Zocor): (1)

l. Other, *(specify):* (1)

_____

58. Has the patient taken any antiobesity medications in the past 3 months:

(Yes 1) (No 2)

59.

(If yes, check all that apply):

a. Dexfenfluramine hydrochloride (Redux): (1)

b. Fenfluramine hydrochloride (Pondimin): (1)

c. Methamphetamine hydrochloride (Desoxyn, Gradumet): (1)

d. Orlistat (Xenical): (1)

e. Phendimetrazine tartrate (Adipost, Bontril): (1)

f. Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine): (1)

g. Sibutramine hydrochloride monohydrate (Meridia): (1)

h. Other, *(specify):* (1)

_____

59. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 3 months:

Yes (1) No (2)

60.

(If yes, check all that apply):

a. Acetaminophen (Tylenol): (1)

b. Aspirin - 325 mg: (1)

c. Aspirin - 81 mg: (1)

d. Celecoxib (Celebrex): (1)

e. Ibuprofen (Advil, Motrin): (1)

f. Indomethacin (Indocin): (1)

g. Naproxen (Aleve, Naprosyn): (1)

h. Rofecoxib (Vioxx): (1)

i. Other, *(specify):* (1)

_____

j. Other, *(specify):* (1)

_____

60. Has the patient taken any strong opiates containing acetaminophen medication in the past 3 months:

Yes (1) No (2)

61.

(If yes, check all that apply):

a. Darvocet: (1)

b. Esgic - Plus: (1)

c. Fioricet: (1)

d. Lorcet: (1)

e. Lortab: (1)

f. Norco: (1)

g. Percocet: (1)

h. Talacen: (1)

i. Tylenol #3: (1)

j. Tylenol #4: (1)

k. Tylox: (1)

l. Vicodin: (1)

m. Wygesic: (1)

n. Other, *(specify):* (1)

_____

61. Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications in the past 3 months:

Yes (1) No (2)

62.

(If yes, check all that apply):

a. Cimetidine (Tagamet): (1)

b. Esomeprazole magnesium (Nexium): (1)

c. Famotidine (Pepcid): (1)

d. Lansoprazole (Prevacid): (1)

e. Nizatidine (Axid): (1)

f. Omeprazole (Prilosec): (1)

g. Ranitidine (Zantac): (1)

h. Ranitidine bismuth citrate (Tritec): (1)

i. Antacids, *(specify):* (1)

_____

j. Other, *(specify):* (1)

_____

62. Has the patient taken any anticoagulant/antiplatelet medications in the past 3 months:

Yes (1) No (2)

63.

(If yes, check all that apply):

a. Clopidogrel (Plavix): (1)

b. Dipyridamole: (1)

c. Heparin: (1)

d. Ticlopide (Ticlid): (1)

e. Warfarin (Coumadin): (1)

f. Other, *(specify):* (1)

_____

63. Has the patient taken any systemic corticosteroids in the past 3 months:

( ) Yes (1) ( ) No (2)

64.

(If yes, check all that apply):

a. Betamethasone sodium (Celestone): ( ) (1)

b. Cortisol: ( ) (1)

c. Cortisone: ( ) (1)

d. Dexamethasone (Decadron): ( ) (1)

e. Hydrocortisone (Hydrocortone): ( ) (1)

f. Methylprednisolone (Solu-Medrol): ( ) (1)

g. Prednisolone (Prelone): ( ) (1)

h. Prednisone: ( ) (1)

i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort): ( ) (1)

j. Other, *(specify):* ( ) (1)

_____

64. Has the patient taken any cardiovascular/antihypertensive medications in the past 3 months:

( ) Yes (1) ( ) No (2)

65.

(If yes, check all that apply):

a. Amiodarone (Pacerone): ( ) (1)

b. Amlodipine besylate (Norvasc): ( ) (1)

c. Atenolol (Tenormin): ( ) (1)

d. Benazepril (Lotensin): ( ) (1)

e. Captopril (Capoten): ( ) (1)

f. Clonidine (Catapres): ( ) (1)

g. Digoxin (Lanoxin): ( ) (1)

h. Diltiazem (Cardizem): ( ) (1)

i. Doxazosin (Cardura): ( ) (1)

j. Enalapril (Vasotec): ( ) (1)

k. Felodipine (Plendil): ( ) (1)

l. Furosemide (Lasix): ( ) (1)

m. Hydrochlorothiazide (Esidrix, HydroDIURIL): ( ) (1)

n. Hydrochlorothiazide + triamterene (Dyazide): ( ) (1)

o. Lisinopril (Prinivil, Zestril): ( ) (1)

p. Losartan potassium (Cozaar): ( ) (1)

q. Losartan potassium with hydrochlorothiazide (Hyzaar): ( ) (1)

r. Metoprolol (Lopressor): ( ) (1)

s. Nifedipine (Adalat, Procardia): ( ) (1)

t. Perhexiline maleate: ( ) (1)

u. Propranolol (Inderal): ( ) (1)

v. Quinapril (Accupril): ( ) (1)

w. Terazosin (Hytrin): ( ) (1)

x. Timolol maleate (Blocadren): ( ) (1)

y. Valsartan (Diovan): ( ) (1)

z. Verapamil (Calan): ( ) (1)

aa. Other, *(specify):* ( ) (1)

_____

ab. Other, *(specify):* ( ) (1)

_____

65. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 3 months:

Yes (1) No (2)

66.

(If yes, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

f. Fluoxymesterone (Android-F, Halotestin): (1)

g. Levonorgestrel (Norplant): (1)

h. Medroxyprogesterone (Cycrin, Provera): (1)

i. Megestrol (Megace): (1)

j. Methyltestosterone (Android): (1)

k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin): (1)

l. Norethindrone (Micronor): (1)

m. Norgestrel (Ovrette): (1)

n. Oral contraceptives: (1)

o. Oxandrolone (Oxandrin): (1)

p. Oxymetholone (Anadrol): (1)

q. Progesterone (Prometrium): (1)

r. Raloxifene (Evista): (1)

s. Tamoxifen (Nolvadex): (1)

t. Other, *(specify):* (1)

_____

u. Other, *(specify):* (1)

_____

66. Has the patient taken any allergy or asthma medications in the past 3 months:

Yes (1) No (2)

67.

(If yes, check all that apply):

a. Beclomethasone dipropionate (Beclovent, Vanceril): (1)

b. Budesonide (Pulmicort, Rhinocort): (1)

c. Fluticasone propionate (Flonase, Flovent): (1)

d. Loratadine (Claritin): (1)

e. Mometasone furoate (Nasonex): (1)

f. Triamcinolone acetonide (Azmacort, Nasacort): (1)

g. Other, *(specify):* (1)

_____

h. Other, *(specify):* (1)

_____

67. Has the patient taken a multivitamin regularly in the past 3 months:

Yes (1) No (2)

68. Has the patient taken vitamins other than multivitamins in the past 3 months:

Yes (1) No (2)

70.

69. Which vitamins has the patient taken *(check all that apply):*

a. Vitamin B (any type): (1)

b. Vitamin C: (1)

c. Vitamin D: (1)

d. Vitamin E: (1)

e. Other, *(specify):* (1)

_____

70. Has the patient taken any supplements in the past 3 months:

Yes (1) No (2)

71.

(If yes, check all that apply):

a. Alpha-lipoic acid: (1)

b. Alpha-tocopherol: (1)

c. Beta-carotene: (1)

d. Betaine (Cystadane): (1)

e. Calcium (any form): (1)

f. Carnitine (any form): (1)

g. Chondroitin (any form): (1)

h. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): (1)

i. Cod liver oil: (1)

j. Coenzyme Q: (1)

k. Dichloroacetate: (1)

l. Echinacea: (1)

m. Fish oil (any form): (1)

n. Flax seed oil: (1)

o. Garlic: (1)

p. Ginkgo biloba: (1)

q. Glucosamine (any form): (1)

r. Lecithin: (1)

s. Magnesium: (1)

t. Milk thistle: (1)

u. N-acetyl-cysteine: (1)

v. Potassium (any form): (1)

w. S-adenylmethionine (SAM-e): (1)

x. Saw palmetto: (1)

y. Selenium: (1)

z. St. John's Wort: (1)

aa. Taurine: (1)

ab. Zinc picolinate: (1)

ac. Other, *(specify):* (1)

_____

ad. Other, *(specify):* (1)

_____

71. Has patient taken any of the following medications or other supplements/medications in the past 3 months:

Yes (1) No (2)

72.

(If yes, record all other supplements/medications):

a. Demeclocycline (Declomycin): (1)

b. Divalproex (Depakote): (1)

c. Doxycycline (Monodox): (1)

d. Isotretinoin (Accutane): (1)

e. Levothyroxine (Levoxyl, Synthroid): (1)

f. Liothyronine (Cytomel): (1)

g. Methotrexate (Rheumatrex): (1)

h. Minocycline (Dynacin, Minocin): (1)

i. Oxytetracycline (Terramycin): (1)

j. Penicillamine (Cuprimine, Depen): (1)

k. Tetracycline (Achromycin): (1)

l. Trientine hydrochloride (Syprine): (1)

m. Ursodeoxycholic acid (Actigall, Urso, Ursodiol): (1)

n. Valproate sodium (Depacon): (1)

o. Valproic acid (Depakene): (1)

p. Other, *(specify):* (1)

_____

q. Other, *(specify):* (1)

_____

r. Other, *(specify):* (1)

_____

I. Administrative information

72. Study Physician PIN: ____ ____ ____

73. Study Physician signature:

_____

74. Clinical Coordinator PIN: ____ ____ ____

75. Clinical Coordinator signature:

_____

76. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

BQ – Beverage Questionnaire (BEVQ-15)

Purpose: To obtain the patient's beverage intake.
When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.
By whom: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient or completed by patient with parental assistance.
Instructions: The Clinical Coordinator should complete section A and attach a label to page 2 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to page 2 and the Clinical Coordinator should complete section C.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit :

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: t _____ _____ _____

6. Form & revision: b q 1

7. Study: NAFLD Database 2 6

C. Administrative information

(To be completed by clinical center staff after survey is completed.)

24. Clinical Coordinator PIN: ____ ____ ____

25. Clinical Coordinator signature:

_____

26. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Citation: Hedrick VE, Savla J, Comber DL, Flack KD, Estabrooks PA, Nsiah-Kumi PA, Ortmeier S, Davy BM. Development of a Brief Questionnaire to Assess Habitual Beverage Intake (BEVQ-15): Sugar-Sweetened Beverages and Total Beverage Energy Intake. J Acad Nutr Diet. 2012; 112:840-849.

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___ ___

B. Instructions: In the past month, please indicate your response for each beverage type by circling the best response for "how often" and "how much each time".

1) Indicate how often you drank the following beverages, for example, if you drank 5 glasses of water per week, circle response "3" under the column labeled "4-6 time per week".

2) Indicate the approximate amount of beverage you drank each time, for example, you drank 1 cup of water each time, circle response "2" under the column labeled "8 fl oz (1 cup)" under "how much each time.

3) Do not count beverages used in cooking or other preparations, such as milk in cereal.

4) Count milk added to tea and coffee in the *tea/coffee with cream beverage category* **NOT** in the milk categories.

#		**a.**							**b.**				
		How often *(circle one)*							**How much each time *(circle one)***				
	Type of beverage	**Never or less than 1 time per week (go to next beverage)**	**1 time per week**	**2-3 times per week**	**4-6 times per week**	**1 time per day**	**2+ times per day**	**3+ times per day**	**Less than 6 fl oz *(3/4 cup)***	**8 fl oz *(1 cup)***	**12 fl oz *(1 ½ cups)***	**16 fl oz *(2 cups)***	**More than 20 fl oz *(2 ½ cups)***
8.	Water	0	1	2	3	4	5	6	1	2	3	4	5
9.	100% Fruit Juice	0	1	2	3	4	5	6	1	2	3	4	5
10.	Sweetened Juice Beverage/ Drink (fruit ades, lemonade, punch, Sunny Delight)	0	1	2	3	4	5	6	1	2	3	4	5
11.	Whole Milk	0	1	2	3	4	5	6	1	2	3	4	5
12.	Reduced Fat Milk (2%)	0	1	2	3	4	5	6	1	2	3	4	5
13.	Low Fat/Fat Free Milk (Skim, 1%, Buttermilk, Soymilk)	0	1	2	3	4	5	6	1	2	3	4	5
14.	Soft Drinks, Regular	0	1	2	3	4	5	6	1	2	3	4	5
15.	Diet Soft Drinks/Artificially Sweetened Drinks (Crystal Light)	0	1	2	3	4	5	6	1	2	3	4	5
16.	Sweetened Tea	0	1	2	3	4	5	6	1	2	3	4	5
17.	Tea or Coffee, with cream and/or sugar (includes non-dairy creamer)	0	1	2	3	4	5	6	1	2	3	4	5
18.	Tea or Coffee, black, with/ without artificial sweetener (no cream or sugar)	0	1	2	3	4	5	6	1	2	3	4	5
19.	Beer, Ales, Wine Coolers, Non-alcoholic or Light Beer	0	1	2	3	4	5	6	1	2	3	4	5
20.	Hard Liquor (shots, rum tequila, etc.)	0	1	2	3	4	5	6	1	2	3	4	5
21.	Wine (red or white)	0	1	2	3	4	5	6	1	2	3	4	5
22.	Energy or Sport Drinks (Red Bull, Rockstar, Gatorade, Powerade, etc.)	0	1	2	3	4	5	6	1	2	3	4	5
23.	Other *(specify)*: _____	0	1	2	3	4	5	6	1	2	3	4	5

Citation: Hedrick VE, Savla J, Comber DL, Flack KD, Estabrooks PA, Nsiah-Kumi PA, Ortmeier S, Davy BM. Development of a Brief Questionnaire to Assess Habitual Beverage Intake (BEVQ-15): Sugar-Sweetened Beverages and Total Beverage Energy Intake. J Acad Nutr Diet. 2012; 112:840-849.

NAFLD Database 2

CG - Genetic Consent and Blood Collection Documentation

Purpose: To document options selected for use of blood samples for genetic research.

When: Visit t0 or as needed during follow-up (during follow-up, use the visit code of the follow-up visit that is open).

By whom: Study Physician, Clinical Coordinator and laboratory personnel responsible for collection of blood.

Instructions: Complete this form based on the consent documents signed by the patient/parent. If the patient changes his/her mind regarding consent for use of samples after the initial form is completed, complete a new CG form. If the patient consents, (1) Fill two 10 mL EDTA vacutainer tubes with blood. (2) Pack and ship the blood in the EDTA tubes to the NIDDK Genetics Repository at Rutgers University on the same day blood is collected. Ship at ambient room temperature. Ship blood in the specimen shippers supplied by the NIDDK Genetics Repository.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: c g 1

7. Study: NAFLD Database 2 6

B. Consent for collection, storage, and use of blood samples for current and future genetic research

8. Has a sufficient yield of DNA (≥100 micrograms) been banked at the NIDDK Genetics Repository for this participant in a previous NASH CRN study:

Yes (1) No (2)

10. ____

9. For which study was it collected *(check all that apply):*

a. Database (1)

b. PIVENS (1)

c. TONIC (1)

d. Other, *(specify):* (1)

_____
specify

20. ____

10. Does the patient/parent consent to genetic research on NAFLD or NASH-related cirrhosis that is currently planned by the study investigators:

Yes (1) No (2)

11. Does the patient/parent consent to future genetic research on NAFLD or NASH-related cirrhosis by this study or other study investigators:

Yes (1) No (2)

12. Does the patient/parent consent to future genetic research not related to NAFLD or NASH-related cirrhosis by this study or other study investigators:

Yes (1) No (2)

13. Other information related to consent for genetic research that clinic staff feel needs to be keyed to the study database *(e.g., if your genetic consent had other options that are not covered by the 3 categories of use of samples specified above):*

_____

_____

_____

_____

_____

14. In your judgment, has the patient/parent consented to collection of blood for DNA banking *(this question is asked in recognition that not all IRBs will have approved consent statements that include language that can be mapped into the questions in items 10 through 12; a response of "No" to this question (item 14) means that blood should NOT be collected for sending to the Genetics Repository and if already collected, should be destroyed by the Genetics Repository):*

Yes (1) No (2)

20. ___

C. Specimen for Genetics Repository

Attach ID labels to two 10mL EDTA tubes and fill each with blood; invert each tube gently 6 times to mix blood with additives; keep tubes at room temperature until the same day shipment to the NIDDK Genetics Repository.

15. Was blood collected today for the NIDDK Genetics Repository:

Yes (1)

16. ___

No, *(specify):* (2)

_____
specify

20. ___

16. Date and time of blood draw

a. Date: ____ ____–____ ____ ____–____ ____
day mon year

b. Time: ____ ____ : ____ ____ (1) (2)
hour minute am pm

17. Number of 10 mL EDTA tubes: ____

18. Form copy of tube labels:

NAFLD DB 2 Form CG
Pt: ccc- 9999, xyz
Gender
Age, yrs.: XX

19. Phlebotomist:

_____
print name

D. Administrative information

20. Study Physician PIN: ____ ____ ____

21. Study Physician signature:

_____

22. Clinical Coordinator PIN: ____ ____ ____

23. Clinical Coordinator signature:

_____

24. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

CG - Genetic Consent and Blood Collection Documentation

Purpose: To document options selected for use of blood samples for genetic research.

When: Visit t0 or as needed during follow-up (during follow-up, use the visit code of the follow-up visit that is open).

By whom: Study Physician, Clinical Coordinator and laboratory personnel responsible for collection of blood.

Instructions: Complete this form based on the consent documents signed by the patient/parent. If the patient changes his/her mind regarding consent for use of samples after the initial form is completed, complete a new CG form. If the patient consents, (1) Fill one 10 mL EDTA vacutainer tube with blood. (2) Pack and ship the blood in the EDTA tube to the NIDDK Genetics Repository at Rutgers University on the same day blood is collected. Ship at ambient room temperature. Ship blood in the specimen shippers supplied by the NIDDK Genetics Repository.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: c g 2

7. Study: NAFLD Database 2 6

B. Consent for collection, storage, and use of blood samples for current and future genetic research

8. Has a sufficient yield of DNA (≥100 micrograms) been banked at the NIDDK Genetics Repository for this participant in a previous NASH CRN study:

(Yes 1) (No 2)

10.

9. For which study was it collected *(check all that apply):*

a. Database (1)

b. PIVENS (1)

c. TONIC (1)

d. Other, *(specify):* (1)

_____
specify

20.

10. Does the patient/parent consent to genetic research on NAFLD or NASH-related cirrhosis that is currently planned by the study investigators:

(Yes 1) (No 2)

11. Does the patient/parent consent to future genetic research on NAFLD or NASH-related cirrhosis by this study or other study investigators:

(Yes 1) (No 2)

12. Does the patient/parent consent to future genetic research not related to NAFLD or NASH-related cirrhosis by this study or other study investigators:

(Yes 1) (No 2)

13. Other information related to consent for genetic research that clinic staff feel needs to be keyed to the study database *(e.g., if your genetic consent had other options that are not covered by the 3 categories of use of samples specified above):*

_____

_____

_____

_____

_____

14. In your judgment, has the patient/parent consented to collection of blood for DNA banking *(this question is asked in recognition that not all IRBs will have approved consent statements that include language that can be mapped into the questions in items 10 through 12; a response of "No" to this question (item 14) means that blood should NOT be collected for sending to the Genetics Repository and if already collected, should be destroyed by the Genetics Repository):*

Yes (1) No (2)

20. ___

C. Specimen for Genetics Repository

Attach ID label to one 10mL EDTA tube and fill with blood; invert the tube gently 6 times to mix blood with additives; keep tube at room temperature until the same day shipment to the NIDDK Genetics Repository.

15. Was blood collected today for the NIDDK Genetics Repository:

Yes (1)

16. ___

No, *(specify):* (2)

_____
specify

20. ___

16. Date and time of blood draw

a. Date:

___ ___–___ ___ ___–___ ___
day mon year

b. Time:

___ ___ : ___ ___ (1) am (2) pm
hour minute

17. Number of 10 mL EDTA tubes: ___

18. Form copy of tube label:

NAFLD DB 2 Form CG
Pt: ccc- 9999, xyz
Gender
Age, yrs.: XX

19. Phlebotomist:

_____
print name

D. Administrative information

20. Study Physician PIN: ___ ___ ___

21. Study Physician signature:

_____

22. Clinical Coordinator PIN: ___ ___ ___

23. Clinical Coordinator signature:

_____

24. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

Central Histology Review

Purpose: Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.
When: Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.
By whom: Data Coordinating Center staff.
Instructions: Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

A. Clinic, patient and visit identification

__ __ __ __ 1. Center ID

__ __ __ __ 2. Patient ID

__ __ __ 3. Patient code

__ __ / __ __ __ / __ __ 4. Date of central reading

__ __ __ __ 5. Visit code

c r 2 6. Form and revision

__ 7. Study: **6**=Database 2; **7**=FLINT

__ __ / __ __ __ / __ __ 8. Date of biopsy

B. Slide sequence number

9. Sequence number for

__ __ . . . a. H & E stained slide

__ __ . . . b. Masson's trichrome stained slide

__ __ . . . c. Iron stained slide

C. Adequacy of biopsy

__ __ 10. Biopsy length (mm)

__ 11. Tissue adequate: **0**=No ➜ Request original slides from submitting clinic; **1**=Yes

_____ 12. Followup with clinic (*Specify*):

D. Histology

H & E stain

13. Steatosis (assume macro, e.g., large and small droplet)

_____ . . . a. Grade: **0**=<5%; **1**=5-33%; **2**=34-66%; **3**=>66%

_____ . . . b. Location: **0**=Zone 3 (*central*); **1**=Zone 1 (*periportal*); **2**=Azonal; **3**=Panacinar

_____ . . . c. Type of macrovesicular steatosis: **0**=Predominantly large droplet; **1**=Mixed large and small droplet; **2**=Predominantly small droplet

_____ . . . d. Microvesicular steatosis, contiguous patches: **0**=Absent; **1**=Present

14. Inflammation

_____ . . . a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci:
0=0; **1**=<2 under 20x mag; **2**=2-4 under 20 mag; **3**=>4 under 20 mag

_____ . . . b. Micrograniulomas seen: **0**=No; **1**=Yes

_____ . . . c. Large lipogranulomas seen: **0**=No; **1**=Yes

_____ . . . d. Amount of portal, chronic inflammation: **0**=None; **1**=Mild; **2**=More than mild

15. Liver cell injury

_____ . . . a. Ballooning: **0**=None ➡ **GOTO Item 15d**; **1**=Few; **2**=Many

_____ . . . b. Severe ballooning present: **0**=No; **1**=Yes

_____ . . . c. Classical balloon cells present: **0**=No; **1**=Yes

_____ . . . d. Acidophil bodies: **0**=Rare/absent; **1**=Many

_____ . . . e. Pigmented macrophages (*Kupffer cells*): **0**=Rare/absent; **1**=Many

_____ . . . f. Megamitochondria: **0**=Rare/absent; **1**=Many

_____ 16. Mallory-Denk bodies: **0**=Rare/absent; **1**=Many

_____ 17. Glycogen nuclei: **0**=Rare/absent; **1**=Present in patches

_____ 18. Glycogenosis of hepatocytes: **0**=Not present; **1**=Focal, involving less than 50% of the hepatocytes; **2**=Diffuse, involving greater than or equal to 50% of the hepatocytes

19. **Masson's trichrome stain**

_____ . . . a. Fibrosis stage: **0**=None ➡ **GOTO Item 20**; **1a**=Mild, zone 3 perisinusoidal (*requires trichrome*); **1b**=Moderate, zone 3, perisinusoidal (*does not require trichrome*); **1c**=Portal/periportal only; **2**=Zone 3 and periportal, any combination; **3**=Bridging; **4**=Cirrhosis

_____ . . . b. Perisinusoidal fibrosis grade: **0**=No perisinusoidal fibrosis present; **1**=Perisinusoidal fibrosis present that requires a Masson stain to identify; **2**=Perisinusoidal fibrosis present that is visible on the H&E stain

_____ . . . c. Predominant location of fibrosis: **0**=More predominance around or between portal areas; **1**=No portal or central predominance; **2**=More predominance around/between central veins

20. **Iron stain**

_____ . . . a. Hepatocellular iron grade: **0**=Absent or barely discernible, 40x ➡ **GOTO item 20c**; **1**=Barely discernable granules, 20x; **2**=Discrete granules resolved, 10x; **3**=Discrete granules resolved, 4x; **4**=Masses visible by naked eye

_____ . . . b. Hepatocellular iron distribution: **0**=Periportal; **1**=Periportal and midzonal; **2**=Panacinar; **3**=Zone 3 or azonal

_____ . . . c. Nonhepatocellular iron grade: **0**=None ➡ **GOTO item 21**; **1**=Mild; **2**=More than mild

_____ . . . d. Nonhepatocellular iron distribution: **0**=Large vessel endothelium only; **1**=Portal/fibrosis bands only, but more than just in large vessel endothelium; **2**=Intraparenchymal only; **3**=Both portal and intraparenchymal

_____ 21. Is this steatohepatitis? **99**=Not NAFLD; **0**=NAFLD, not NASH; **1a**=Suspicious/borderline/indeterminate: Zone 3 pattern; **1b**=Suspicious/borderline/indeterminate: Zone 1, periportal pattern; **2**=Yes, definite

_____ 22. Is cirrhosis present? **0**=No ➡ **GOTO item 25**; **1**=Yes

_____ 23. Is this cryptogenic cirrhosis: **0**=No ➡ **GOTO item 25**; **1**=Yes

24. Features suggestive of steatohepatitis etiology for cryptogenic cirrhosis:

_____ . . . a. Mallory-Denk bodies (*rule out cholate stasis*): **0**=Absent; **1**=Present

_____ . . . b. Perisinusoidal fibrosis away from septa: **0**=Absent; **1**=Present

_____ . . . c. Hepatocyte ballooning: **0**=Absent; **1**=Present

_____ . . . d. Megamitochondria: **0**=Absent; **1**=Present

_____ . . . e. Other notable findings: **0**=Absent; **1**=Present; Specify: _____

25. Other comments: _____

Central Histology Review

Purpose: Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.
When: Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.
By whom: Data Coordinating Center staff.
Instructions: Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

A. Clinic, patient and visit identification

__ __ __ __ 1. Center ID

__ __ __ __ 2. Patient ID

__ __ __ 3. Patient code

__ __ / __ __ __ / __ __ 4. Date of central reading

__ __ __ __ 5. Visit code

c r 3 6. Form and revision

__ 7. Study: **6**=Database 2; **9**=STOP-NAFLD

__ __ / __ __ __ / __ __ 8. Date of biopsy

B. Slide sequence number

9. Sequence number for

__ __ . . . a. H & E stained slide

__ __ . . . b. Masson's trichrome stained slide

__ __ . . . c. Iron stained slide

C. Adequacy of biopsy

__ __ 10. Biopsy length (mm)

__ 11. Tissue adequate: **0**=No ➜ Request original slides from submitting clinic; **1**=Yes

_____ 12. Followup with clinic (*Specify*):

D. Histology

_____ *Patient ID*

H & E stain

13. Steatosis (assume macro, e.g., large and small droplet)

_____ . . . a. Grade: **0**=<5%; **1**=5-33%; **2**=34-66%; **3**=>66%

_____ . . . b. Location: **0**=Zone 3 (*central*); **1**=Zone 1 (*periportal*); **2**=Azonal; **3**=Panacinar

_____ . . . c. Type of macrovesicular steatosis: **0**=Predominantly large droplet; **1**=Mixed large and small droplet; **2**=Predominantly small droplet

_____ . . . d. Microvesicular steatosis, contiguous patches: **0**=Absent; **1**=Present

14. Inflammation

_____ . . . a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci: **0**=0; **1**=<2 under 20x mag; **2**=2-4 under 20 mag; **3**=>4 under 20 mag

_____ . . . d. Amount of portal, chronic inflammation: **0**=None; **1**=Mild; **2**=More than mild

15. Liver cell injury

_____ . . . a. Ballooning: **0**=None ➜ **GOTO Item 15d**; **1**=Few; **2**=Many

_____ . . . b. Severe ballooning present: **0**=No; **1**=Yes

_____ . . . c. Classical balloon cells present: **0**=No; **1**=Yes

_____ . . . d. Acidophil bodies: **0**=Rare/absent; **1**=Many

_____ . . . f. Megamitochondria: **0**=Rare/absent; **1**=Many

_____ 16. Mallory-Denk bodies: **0**=Rare/absent; **1**=Many

_____ 18. Glycogenosis of hepatocytes: **0**=Not present; **1**=Focal, involving less than 50% of the hepatocytes; **2**=Diffuse, involving greater than or equal to 50% of the hepatocytes

19. **Masson's trichrome stain**

_____ . . . a. Fibrosis stage: **0**=None ➜ **GOTO Item 20**; **1a**=Mild, zone 3 perisinusoidal (*requires trichrome*); **1b**=Moderate, zone 3, perisinusoidal (*does not require trichrome*); **1c**=Portal/periportal only; **2**=Zone 3 and periportal, any combination; **3**=Bridging; **4**=Cirrhosis

_____ . . . b. Perisinusoidal fibrosis grade: **0**=No perisinusoidal fibrosis present; **1**=Perisinusoidal fibrosis present that requires a Masson stain to identify; **2**=Perisinusoidal fibrosis present that is visible on the H&E stain

_____ . . . c. Predominant location of fibrosis: **0**=More predominance around or between portal areas; **1**=No portal or central predominance; **2**=More predominance around/between central veins

20. **Iron stain**

_____ . . . a. Hepatocellular iron grade: **0**=Absent or barely discernible, 40x ➜ **GOTO item 20c**; **1**=Barely discernable granules, 20x; **2**=Discrete granules resolved, 10x; **3**=Discrete granules resolved, 4x; **4**=Masses visible by naked eye

_____ . . . b. Hepatocellular iron distribution: **0**=Periportal; **1**=Periportal and midzonal; **2**=Panacinar; **3**=Zone 3 or azonal

_____ . . . c. Nonhepatocellular iron grade: **0**=None ➜ **GOTO item 21**; **1**=Mild; **2**=More than mild

_____ . . . d. Nonhepatocellular iron distribution: **0**=Large vessel endothelium only; **1**=Portal/fibrosis bands only, but more than just in large vessel endothelium; **2**=Intraparenchymal only; **3**=Both portal and intraparenchymal

_____ 21. Is this steatohepatitis? **99**=Not NAFLD; **0**=NAFLD, not NASH; **1a**=Suspicious/borderline/indeterminate: Zone 3 pattern; **1b**=Suspicious/borderline/indeterminate: Zone 1, periportal pattern; **2**=Yes, definite

25. Other comments: _____

Central Histology Review

Purpose: Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.
When: Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.
By whom: Data Coordinating Center staff.
Instructions: Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

A. Clinic, patient and visit identification

__ __ __ __ 1. Center ID

__ __ __ __ 2. Patient ID

__ __ __ 3. Patient code

__ __ / __ __ __ / __ __ 4. Date of central reading

__ __ __ __ 5. Visit code

c r 4 6. Form and revision

__ 7. Study: **10**=VEDS; **11**=Database 3

__ __ / __ __ __ / __ __ 8. Date of biopsy

B. Slide sequence number

9. Sequence number for

__ __ . . . a. H & E stained slide

__ __ . . . b. Masson's trichrome stained slide

__ __ . . . c. Iron stained slide

C. Adequacy of biopsy

__ __ 10. Biopsy length (mm)

__ 11. Tissue adequate: **0**=No ➜ Request original slides from submitting clinic; **1**=Yes

_____ 12. Followup with clinic (*Specify*):

D. Histology

_____ *Patient ID*

H & E stain

13. Steatosis (assume macro, e.g., large and small droplet)

_____ . . . a. Grade: **0**= <5%; **1**= 5-33%; **2**= 34-66%; **3**= >66%

_____ . . . b. Location: **0**=Zone 3 (*central*); **1**=Zone 1 (*periportal*); **2**=Azonal; **3**=Panacinar

_____ . . . c. Type of macrovesicular steatosis: **0**=Predominantly large droplet; **1**=Mixed large and small droplet; **2**=Predominantly small droplet

_____ . . . d. Microvesicular steatosis, contiguous patches: **0**=Absent; **1**=Present

14. Inflammation

_____ . . . a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci: **0**=0; **1**=<2 under 20x mag; **2**=2-4 under 20 mag; **3**=>4 under 20 mag

_____ . . . b. Amount of portal, chronic inflammation: **0**=None; **1**=Mild; **2**=More than mild

_____ . . . c. Amount of portal, chronic inflammation, expanded: **0**=None; **1**=Minimal; **2**=Mild; **3**=Moderate; **4**=Severe

_____ . . . d. Amount of periportal inflammation: **0**=None; **1**=1-2 foci; **2**=>2 foci to 1/3 of circumference; **3**=1/3 to 2/3 of circumference; **4**=>2/3 of circumference

_____ . . . e. Ductular reaction: **0**=None; **1**=1-2 ductules; **2**=3-5 ductules; **3**=6-10 ductules; **4**=>10 ductules

15. Liver cell injury

_____ . . . a. Ballooning: **0**=None ➜ **GOTO Item 15d**; **1**=Few; **2**=Many

_____ . . . b. Severe ballooning present: **0**=No; **1**=Yes

_____ . . . c. Classical balloon cells present: **0**=No; **1**=Yes

_____ 16. Mallory-Denk bodies: **0**=Rare/absent; **1**=Many

17. **Masson's trichrome stain**

_____ . . . a. Fibrosis stage: **0**=None ➜ **GOTO Item 20**; **1a**=Mild, zone 3 perisinusoidal (*requires trichrome*); **1b**=Moderate, zone 3, perisinusoidal (*does not require trichrome*); **1c**=Portal/periportal only; **2**=Zone 3 and periportal, any combination; **3a**=Early bridging; **3b**=Advanced bridging; **4a**=Early cirrhosis; **4b**=Advanced cirrhosis

_____ . . . b. Perisinusoidal fibrosis grade: **0**=No perisinusoidal fibrosis present; **1**=Perisinusoidal fibrosis present that requires a Masson stain to identify; **2**=Perisinusoidal fibrosis present that is visible on the H&E stain

_____ . . . c. Predominant location of fibrosis: **0**=More predominance around or between portal areas; **1**=No portal or central predominance; **2**=More predominance around/between central veins

18. **Iron stain**

_____ . . . a. Hepatocellular iron grade: **0**=Absent or barely discernible, 40x ➜ **GOTO item 20c**; **1**=Barely discernable granules, 20x; **2**=Discrete granules resolved, 10x; **3**=Discrete granules resolved, 4x; **4**=Masses visible by naked eye

_____ . . . b. Hepatocellular iron distribution: **0**=Periportal; **1**=Periportal and midzonal; **2**=Panacinar; **3**=Zone 3 or azonal

_____ . . . c. Nonhepatocellular iron grade: **0**=None ➜ **GOTO item 21**; **1**=Mild; **2**=More than mild

_____ . . . d. Nonhepatocellular iron distribution: **0**=Large vessel endothelium only; **1**=Portal/fibrosis bands only, but more than just in large vessel endothelium; **2**=Intraparenchymal only; **3**=Both portal and intraparenchymal

_____ 19. Is this steatohepatitis? **99**=Not NAFLD; **0**=NAFLD, not NASH; **1a**=Suspicious/borderline/indeterminate: Zone 3 pattern; **1b**=Suspicious/borderline/indeterminate: Zone 1, periportal pattern; **2**=Yes, definite

_____ 20. Features of regression: **0**=No; **1**=Yes

21. Other comments: _____

NAFLD Database 2

Cardiovascular Risk Factors

Purpose: To determine a patient's need for referral for cholesterol management based on the Adult Treatment Panel III (ATP III) cholesterol guidelines.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: Clinic coordinator by interview with patient and medical chart review.

Respondent: Patient age 18 or older.

Instructions: Collect information by interview, chart review, and by transcribing data from the Database 2 Physical Examination (PE), Laboratory Results (LR), and Baseline (BG) or Follow-up (HI) Medical History forms. The anthropometric, blood pressure, and laboratory values reported on this form should be those collected at the same visit.

Important: Key the CV form only after you have keyed the BG/HI, LR, and PE forms.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t ____ ____ ____

6. Form & revision: c v 1

7. Study: NAFLD Database 2 6

B. Framingham Risk Assessment

8. Was a lipid panel obtained at this visit:

Yes (1) No (2) → **21.**

9. Gender

Male (1)
Female (2)

10. Age: ____ ____ years

11. Are you a current cigarette smoker:

Yes (1) No (2)

12. Total cholesterol *(from LR form):*

____ ____ ____ mg/dL

If the patient has total cholesterol greater than 300 mg/dL, an IE form should be completed.

13. HDL cholesterol *(from LR form):*

____ ____ ____ mg/dL

14. LDL cholesterol *(from LR form)*:*

____ ____ ____ mg/dL

**Enter "GT" if LDL cannot be calculated due to high triglycerides.*

15. Blood pressure

a. Systolic blood pressure *(from PE form):*

____ ____ ____ mmHg

b. Diastolic blood pressure *(from PE form):*

____ ____ ____ mmHg

16. Are you currently being treated for high blood pressure with medicine prescribed by your doctor:

Yes (1) No (2)

17. Has anyone in your immediate family *(blood-related parent, brother, sister, or child)* been diagnosed with early heart disease *(before age 55 years for male relatives and before 65 years for female relatives):*

Yes (1) No (2)

18. Framingham point scores *(use the ATP III At-a-Glance Quick Desk Reference [NIH Publication No. 01-3305] on page 4 to record gender-specific scores based on the patient's risk factors. Circle ''+'' or ''-'' as appropriate. Key + # or - #; if 0 for an item with +/-, key ''+0'' or ''+00''.)*

a. Age score
(based on item 10; if the patient's age is 18 or 19, use the 20-34 age range):
+ / - ____ ____ points

b. Total cholesterol score
(based on items 10 and 12): ____ ____ points

c. Smoking score
(based on items 10 and 11): ____ points

d. HDL score *(based on item 13):* + / - ____ points

e. Systolic blood pressure score *(based on items 15a and 16):* ____ points

19. Point total *(Add items 18a-e):* + / - ____ ____ points

20. Framingham risk of heart attack or dying of coronary heart disease in the next 10 years *(using the ATP-III at-a-glance publication on page 4, use the point total [item 19] to convert into gender-specific 10 year risk):*

____ ____ %

If 10 year risk % < 1, record ''00''. If 10 year risk % ≥ 30, record ''30''.

C. ATP III guidelines

21. Have you been diagnosed with type 1 or type 2 diabetes:

Yes (1) No (2)

22. Have you been diagnosed with clinical atherosclerotic disease that confers high risk for coronary heart disease (CHD) events (CHD risk equivalent):

Yes (1) No (2)

23.

(If yes, check all that apply)

a. Clinical CHD: (1)

b. Symptomatic carotid artery disease: (1)

c. Peripheral arterial disease: (1)

d. Abdominal aortic aneurysm: (1)

23. Was ''Yes'' checked for either item 21 or 22 or was LDL unknown (''GT'' in item 14 or lipid panel not obtained):

Yes (1) No (2)

25.

24. Is 10-year Framingham heart attack risk estimate 22% (item 20) or more:

Yes (1) No (2)

27.

25. Is LDL cholesterol (item 14) less than 100 mg/dL or was LDL unknown (''GT'' in item 14 or lipid panel not obtained):

Yes (1) No (2)

34.

26. Is LDL cholesterol (item 14) 130 mg/dL or more:

Yes (*1) No (†2)

34. **34.**

**Refer for cholesterol management with LDL-lowering drug therapy (see Database 2 SOP V).*

†Refer for cholesterol management with drug therapy optional, initiate LDL-lowering therapeutic lifestyle changes (see Database 2 SOP V).

27. Coronary heart disease (CHD) risk factors: Do you have any of the following:

a. Current cigarette smoking *(based on item 11):* (1)

b. SBP ≥ 140 mmHg or DBP ≥ 90 mmHg or on antihypertensive medication *(based on items 15 and 16):* (1)

c. HDL cholesterol less than 40 mg/dL *(based on item 13):* (1)

d. Family history of premature CHD *(based on item 17):* (1)

e. Age in men ≥ 45 years or age in women ≥ 55 years *(based on items 9 and 10):* (1)

f. HDL cholesterol 60 mg/dL or more *(based on item 13):* (1)

28. Total number of CHD risk factors *(add number of "yes" in items 27a-e and subtract 1 if item 27f is "yes"; code as "0" if only 27f is "yes"):* ____

29. Are there 2 or more CHD risk factors (item 28):

Yes (1) No (2)

32.

30. Is LDL cholesterol less than 130 mg/dL:

Yes (1) No (2)

34.

31. Is 10-year Framingham heart attack risk estimate between 10 and 20%, inclusive or LDL cholesterol 160 mg/dL or more:

Yes (*1) No (†2)

34. 34.

**Refer for cholesterol management with LDL-lowering drug therapy (see Database 2 SOP V).*

†Refer for cholesterol management with drug therapy optional, initiate LDL-lowering therapeutic lifestyle changes (see Database 2 SOP V).

32. Is LDL cholesterol 190 mg/dL or more:

Yes (*1) No (2)

34.

**Refer for cholesterol management with LDL-lowering drug therapy (see Database 2 SOP V).*

33. Is LDL cholesterol between 160 and 189 mg/dL, inclusive:

Yes (†1) No (2)

†Refer for cholesterol management with drug therapy optional, initiate LDL-lowering therapeutic lifestyle changes (see Database 2 SOP V).

D. Other cardiovascular events

34. Has the patient ever been diagnosed with or treated for any of the following *(check all that apply)*

a. Myocardial infarction: (1)

b. Angina: (1)

c. Stroke: (1)

d. Cerebrovascular disease: (1)

e. Coronary artery disease: (1)

f. Congestive heart failure: (1)

g. Peripheral vascular disease: (1)

h. Other cardiovascular disease *(specify):* (1)

_____
specify

i. None of the above: (1)

E. Administrative information

35. Study Physician PIN: ____ ____ ____

36. Study Physician signature:

_____

37. Clinical Coordinator PIN: ____ ____ ____

38. Clinical Coordinator signature:

_____

39. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Men

Estimate of 10-Year Risk for Men

(Framingham Point Scores)

Age	Points
20-34	-9
35-39	-4
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	11
70-74	12
75-79	13

Total Cholesterol	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	0
200-239	7	5	3	1	0
240-279	9	6	4	2	1
≥280	11	8	5	3	1

	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0	0	0	0	0
Smoker	8	5	3	1	1

HDL (mg/dL)	Points
≥60	-1
50-59	0
40-49	1
<40	2

Systolic BP (mmHg)	If Untreated	If Treated
<120	0	0
120-129	0	1
130-139	1	2
140-159	1	2
≥160	2	3

Point Total	10-Year Risk %
<0	< 1
0	1
1	1
2	1
3	1
4	1
5	2
6	2
7	3
8	4
9	5
10	6
11	8
12	10
13	12
14	16
15	20
16	25
≥17	≥ 30

10-Year risk _____%

Women

Estimate of 10-Year Risk for Women

(Framingham Point Scores)

Age	Points
20-34	-7
35-39	-3
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	12
70-74	14
75-79	16

Total Cholesterol	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	1
200-239	8	6	4	2	1
240-279	11	8	5	3	2
≥280	13	10	7	4	2

	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0	0	0	0	0
Smoker	9	7	4	2	1

HDL (mg/dL)	Points
≥60	-1
50-59	0
40-49	1
<40	2

Systolic BP (mmHg)	If Untreated	If Treated
<120	0	0
120-129	1	3
130-139	2	4
140-159	3	5
≥160	4	6

Point Total	10-Year Risk %
< 9	< 1
9	1
10	1
11	1
12	1
13	2
14	2
15	3
16	4
17	5
18	6
19	8
20	11
21	14
22	17
23	22
24	27
≥25	≥ 30

10-Year risk _____%

NAFLD Database 2

DR - Death Report

Purpose: To record the report of a patient's death.
When: As soon as clinic is notified of a patient's death.
Administered by: Study Physician and Clinical Coordinator.
Instructions: Complete and key this form whenever the clinical center is informed of a patient's death. Fax a copy of the Death Report (DR) form to the DCC at (410) 955-0932; Attention: Pat Belt. Also, complete an Interim Event (IE) form and follow the instructions to report a patient's death in the NAFLD Database 2.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form is initiated *(date of notice):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____ ____

6. Form & revision: d r 1

7. Study: NAFLD Database 2 6

B. Death information

8. Date of death:

____ ____–____ ____ ____–____ ____
day mon year

9. Source of death report *(check all that apply):*

a. Patient's family: (1)
b. Friend: (1)
c. Health care provider or NASH CRN staff: (1)
d. Newspaper: (1)
e. Funeral parlor/home: (1)
f. Medical record: (1)
g. Medical examiner: (1)
h. Coroner: (1)
i. Other *(specify):* (1)

_____
other source

_____
other source

10. Place of death:

_____
city/state/country

_____
city/state/country

11. Cause of death
(Study Physician: use whatever knowledge you have and your best medical judgment to best characterize the cause of death; check only one):

Heart disease (1)
Stroke (2)
Liver disease (3)
Malignancy (4)
Other *(specify):* (5)

_____
specify

_____
specify

Unknown (6)

C. Administrative information

12. Study Physician PIN: ____ ____ ____

13. Study Physician signature:

_____

14. Clinical Coordinator PIN: ____ ____ ____

15. Clinical Coordinator signature:

_____

16. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

DR - Death Report

Purpose: To record the report of a patient's death.
When: As soon as clinic is notified of a patient's death.
Administered by: Study Physician and Clinical Coordinator.
Instructions: Complete and key this form whenever the clinical center is informed of a patient's death using as much information about the circumstances of death as possible. Fax a copy of the Death Report (DR) form, including the narrative, and the death certificate (if obtained) to the DCC at (410) 955-0932; Attention: Pat Belt. **Also, complete an Interim Event (IE) form** and follow the instructions to report a patient's death in the NAFLD Database 2. If either the cause or contributing cause of death is hepatocellular carcinoma (HCC), then also complete an Hepatocellular Carcinoma Report (HC) form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form is initiated *(date of notice):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____ ____

6. Form & revision: d r 2

7. Study: NAFLD Database 2 6

B. Death information

8. Date of death:

____ ____–____ ____ ____–____ ____
day mon year

9. Source of death report *(check all that apply):*

a. Patient's family: (1)
b. Friend: (1)
c. Other caregiver: (1)
d. Health care provider or NASH CRN staff: (1)
e. Newspaper: (1)
f. Funeral parlor/home: (1)
g. Medical record: (1)
h. Medical examiner: (1)
i. Coroner: (1)
j. National Death Index (NDI): (1)
k. Social Security Death Master File (SSDMF): (1)
l. Other *(specify):* (1)

_____
other source

_____
other source

10. Place and location of death

a. Place of death *(check only one):*

Hospital (1)
Hospice (2)
Home (3)
Nursing home (4)
Other *(specify):* (5)

_____

Unknown (6)

b. Location of death:

_____
city/state/country

11. Has a death certificate been obtained:

Yes (1) No (2)

If no, please obtain or explain why not:

_____

_____

_____

12. Underlying cause of death *(Study Physician: use whatever knowledge you have to best characterize the primary cause of death);* ***(CHECK ONLY ONE):***

Coronary heart disease (01)
13. ____

Cardiovascular disease (02)
14. ____

Liver disease (03)
15. ____

Malignancy (cancer) (04)
16. ____

Gastrointestinal (GI) disease (05)
17. ____

Pulmonary (lung) disease (06)
18. ____

Pneumonia (07)
19. ____

Complication of diabetes (08)
19. ____

Accident (09)
19. ____

Suicide (10)
19. ____

Homicide (11)
19. ____

Kidney disease or renal failure (12)
19. ____

Sepsis, staph or other infection (13)
19. ____

Multi-organ failure (14)
19. ____

Other *(specify):* (15)
19. ____

_____

Unknown (16)
19. ____

13. CAUSE OF DEATH: Coronary heart disease (CHD) subclassification ***(check only one)****:*

Definite fatal myocardial infarction (MI) or heart attack (1)

Defined as:
1. *Death within 28 days of hospital admission,* ***OR***
2. *Postmortem findings consistent with MI within 28 days of hospital admission,* ***OR***
3. *Documented definite or probable MI in previous 28 days if death occurred out of hospital and no evidence of a noncoronary cause of death,* ***OR***
4. *Autopsy evidence of recent coronary occlusion or MI < 28 days old.*

Probable fatal MI (2)

Defined as:
1. *Death within 28 days of hospital admission in cases defined in probable MI cases,* ***OR***
2. *Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or not diagnostic).*

Definite fatal CHD (3)

Defined as:
1. *A history of CHD and/or documented cardiac pain within 72 hours before death and no evidence of a noncoronary cause of death,* ***OR***
2. *Autopsy evidence of chronic CHD, including coronary atherosclerosis and myocardial scarring.*

Go to 19.

14. CAUSE OF DEATH: Cardiovascular (CVD) disease subclassification ***(check only one)****:*

Congestive heart failure (CHF) (1)

Defined as: Death due to clinical, radiologic or postmortem evidence of CHF without clinical or postmortem evidence of an acute ischemic event (cardiogenic shock included).

Documented arrhythmia (2)

Defined as: Death due to brady- or tachy- arrhythmias not associated with an acute ischemic event.

Cerebrovascular (stroke) (3)

Defined as: Death due to stroke occurring within 7 days of signs and symptoms of stroke or during admission for stroke.

Other cardiovascular (4)

Defined as: Death due to other known vascular diseases including abdominal aortic aneurysm rupture.

Specify: _____

Go to 19.

15. CAUSE OF DEATH: Liver disease subclassification ***(check only one)****:*

- Nonalcoholic fatty liver disease (NAFLD) (1)
- Chronic hepatitis C (2)
- Acute liver failure (3)
- Other *(specify):* (4)

_____

19. ____

16. CAUSE OF DEATH: Malignancy (cancer) subclassification ***(check only one)****:*

- Breast cancer (01)
- Colon cancer (02)
- Endometrial/Uterine cancer (03)
- Esophageal cancer (04)
- Hepatocellular carcinoma (HCC)* (05)
  ** Complete and key the HC form.*
- Ovarian cancer (06)
- Pancreatic cancer (07)
- Prostate cancer (08)
- Rectal cancer (09)
- Other known cancer or malignant tumor *(specify):* (10)

_____

- Unknown cancer site (11)

19. ____

17. CAUSE OF DEATH: Gastrointestinal subclassification ***(check only one)****:*

- Diverticular disease (1)
- *Clostridium difficile* colitis (2)
- Intestinal obstruction (3)
- Ulcer *(gastric, duodenal, peptic, gastrojejunal)* (4)
- Vascular disorders of the intestine (5)
- Other *(specify):* (6)

_____

19. ____

18. CAUSE OF DEATH: Pulmonary (lung) subclassification ***(check only one)****:*

- Asthma (1)
- Acute respiratory failure (2)
- Interstitial lung disease (ILD) (3)
- Other *(specify):* (4)

_____

19. Contributing causes of death ***(check all that apply)****:*

- **a.** Coronary heart disease (CHD) *(specify):* (1)

_____

- **b.** Cerebrovascular disease (stroke): (1)
- **c.** Congestive heart failure (CHF): (1)
- **d.** Documented arrhythmia, not associated with MI: (1)
- **e.** Other cardiovascular disease *(specify):* (1)

_____

- **f.** Diabetes Type 1: (1)
- **g.** Diabetes Type 2: (1)
- **h.** Liver disease *(specify):* (1)

_____

- **i.** Hepatocellular (liver) carcinoma (HCC)*: (1)
  ** Complete and key the HC form.*
- **j.** Other malignancy (cancer) *(specify):* (1)

_____

- **k.** Gastrointestinal (GI) disease *(specify):* (1)

_____

- **l.** Pulmonary (lung) disease *(specify):* (1)

_____

- **m.** Pneumonia: (1)
- **n.** Kidney disease: (1)
- **o.** Sepsis, staph or other infection: (1)
- **p.** Other *(specify):* (1)

_____

- **q.** Unknown: (1)
- **r.** None: (1)

20. Was this a procedure-related death:

(Yes 1) (No 2)

22.

21. Type of procedure-related death ***(check only one)****:*

Cardiac death: Cardiovascular-related procedure
(Defined as death after invasive cardiovascular intervention. Death within 28 days of cardiovascular surgery or within 7 days of cardiac cath, arrhythmia ablation, angioplasty, atherectomy, stent deployment, or other invasive coronary vascular intervention.): (1)

Cardiac death: Noncardiovascular procedure
(Defined as cardiac death after noncardiovascular intervention which occurs within 28 days of surgery or other invasive procedure.): (2)

Non-cardiac death (3)

Unknown (4)

22. Was an autopsy performed ***(check only one)****:*

Yes (1)

No (2)

Unknown (3)

23. Documentation available for future formal death adjudication ***(check all that apply)****:*

a. Medical records documentation: (1)

b. Report of autopsy findings: (1)

c. Death certificate: (1)

d. ER record: (1)

e. EMS report: (1)

f. Informant interview: (1)

g. Coroner's report: (1)

h. Other *(specify):* (1)

_____

24. Include a narrative from the Study Physician summarizing the event of death and comorbidities on **page 6** and Fax a copy to the DCC ((410) 955-0932; Attention Pat Belt).

Narrative is included (1)

Narrative is not included (2)

If not, please explain why not:

_____

_____

C. Administrative information

25. Study Physician PIN: ____ ____ ____

26. Study Physician signature:

_____

27. Clinical Coordinator PIN: ____ ____ ____

28. Clinical Coordinator signature:

_____

29. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Narrative - do not key:

NAFLD Database 2

FR - FibroScan® Report

Purpose: To record key data from the FibroScan® exam.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: NASH CRN certified FibroScan® technician(s) and Study Physician.

IMPORTANT: **FibroScan® examinations may only be performed on NASH CRN patients. DO NOT perform on non-NASH CRN patients, per agreement with manufacturer.**

Instructions: Verify that the patient has understood and signed the FibroScan® consent form. Perform the exam per the procedures in the NAFLD Adult Database 2 SOP I. Briefly, this involves the following:
Before FibroScan® procedure, review the following basic information with patients: 1) Patients must have fasted for three or more hours prior to the FibroScan® procedure (necessary medications are allowed with small amounts of water). 2) Clothing must permit access to the abdomen.
Conduct of the two required FibroScan® procedures: 1) Obtain consent for the FibroScan® procedure. 2) Check that patient has no FibroScan® contraindications (see item 9). 3) Emphasize the need to remain still during the procedure. 4) On the FibroScan® device, enter the patient ID (e.g., 9999) in the Lastname field; enter the letter code (e.g., zyx) in the Firstname field, and enter the visit code followed by NASH in the Code field (e.g., t0 NASH). Enter NAFLD in the Admitting diagnosis field. 5) Position patient supine with right arm raised behind his/her head. 6) Apply a dime-sized amount of water based conduction gel over the liver. 7) Place M or XL probe over liver and obtain 10 valid measurements (if necessary, repeat until you have 10 valid measurements). 8) To choose between M and XL probe, follow the recommendation provided by the device. In case of recommendation fluctuating between M and XL, choose the XL. 9) Save test results, print test report, record results in Section D. 10) Repeat steps 5-9 above for second FibroScan® exam. 11) Record results from the second exam in Section E.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(date of FibroScan® exam):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: f r 1

7. Study: NAFLD Database 2 6

B. Consent

8. Has the patient signed the FibroScan® consent:

(Yes 1) (* No 2)

21. ____

** A FibroScan® exam should not be performed unless consent is obtained.*

9. Does the patient have any of the following contraindications *(check all that apply):*

a. An active implant such as pacemaker, defibrillator, pump, etc.: (1)

b. Wound near the site of scan: (1)

c. Pregnancy: (1)

d. Ascites (fluid in the abdomen): (1)

e. Patient did not fast for 3 hours: (1)

f. Were any of the items above (a-e) checked:

(* Yes 1) (No 2)

21. ____

** If any of the above are checked, the FibroScan® exam SHOULD NOT be performed. Skip to item 21.*

C. FibroScan® Procedure information

10. Was FibroScan® exam performed:

Yes (1) No (*2)

12. ┘

** Complete item 11, then skip to item 21.*

11. Reason FibroScan® exam not performed *(check all that apply):*

a. Patient had a skin-to-capsule distance measurement greater than 3.5cm: (1)

b. Other *(specify):* (1)

_____

Skip to item 21.

12. Probe type used:

M: (1)

XL: (2)

D. FibroScan® exam #1 results

13. FibroScan® Technician PIN: ___ ___ ___

14. Number of valid measurements*: ___ ___
# of measurements

** Note: at least ten valid measurements should be made.*

15. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ ,___ ___
(1,5-75,0)

b. IQR (kPa): ___ ,___ ___

c. IQR/med: ___ ___
%

16. Controlled Attenuation Parameter (CAP) ***(skip if XL probe was used)***

a. Median (dB/m): ___ ___ ___
(100-400)

b. IQR (dB/m): ___ ___ ___

E. FibroScan® exam #2 results

(This may be done by the same technician or a different technician).

17. FibroScan® Technician PIN: ___ ___ ___

18. Number of valid measurements*: ___ ___
# of measurements

** Note: at least ten valid measurements should be made.*

19. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ ,___ ___
(1,5-75,0)

b. IQR (kPa): ___ ,___ ___

c. IQR/med: ___ ___
%

20. Controlled Attenuation Parameter (CAP) ***(skip if XL probe was used)***

a. Median (dB/m): ___ ___ ___
(100-400)

b. IQR (dB/m): ___ ___ ___

F. Administrative information

21. Study Physician PIN: ___ ___ ___

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ___ ___ ___

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

NAFLD Database 2

FR - FibroScan® Report

Purpose: To record key data from the FibroScan® exam.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: NASH CRN certified FibroScan® technician(s) and Study Physician.

IMPORTANT: **FibroScan® examinations may only be performed on NASH CRN patients. DO NOT perform on non-NASH CRN patients, per agreement with manufacturer.**

Instructions: Verify that the patient has understood and signed the FibroScan® consent form. Perform the exam per the procedures in the NAFLD Adult Database 2 SOP I. Briefly, this involves the following:
Before FibroScan® procedure, review the following basic information with patients: 1) Patients must have fasted for three or more hours prior to the FibroScan® procedure (necessary medications are allowed with small amounts of water). 2) Clothing must permit access to the abdomen.
Conduct of the two required FibroScan® procedures: 1) Obtain consent for the FibroScan® procedure. 2) Check that patient has no FibroScan® contraindications (see item 9). 3) Emphasize the need to remain still during the procedure. 4) On the FibroScan® device, enter the patient ID (e.g., 9999) in the Lastname field; enter the letter code (e.g., zyx) in the Firstname field, and enter the visit code followed by NASH in the Code field (e.g., t0 NASH). Enter NAFLD in the Admitting diagnosis field. 5) Position patient supine with right arm raised behind his/her head. 6) Apply a dime-sized amount of water based conduction gel over the liver. 7) Place M or XL probe over liver and obtain 10 valid measurements (if necessary, repeat until you have 10 valid measurements). 8) To choose between M and XL probe, follow the recommendation provided by the device. In case of recommendation fluctuating between M and XL, choose the XL. 9) Save test results, print test report, record results in Section D. 10) Repeat steps 5-9 above for second FibroScan® exam. 11) Record results from the second exam in Section E.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(date of FibroScan® exam):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: f r 2

7. Study: NAFLD Database 2 6

B. Consent

8. Has the patient signed the FibroScan® consent:

Yes (1) No (*2)

21.

** A FibroScan® exam should not be performed unless consent is obtained.*

9. Does the patient have any of the following contraindications *(check all that apply):*

a. An active implant such as pacemaker, defibrillator, pump, etc.: (1)

b. Wound near the site of scan: (1)

c. Pregnancy: (1)

d. Ascites (fluid in the abdomen): (1)

e. Patient did not fast for 3 hours: (1)

f. Were any of the items above (a-e) checked:

Yes (*1) No (2)

21.

** If any of the above are checked, the FibroScan® exam SHOULD NOT be performed. Skip to item 21.*

C. FibroScan® Procedure information

10. Was FibroScan® exam performed:

Yes (1) No (*2)

12.

** Complete item 11, then skip to item 21.*

11. Reason FibroScan® exam not performed *(check all that apply):*

a. Patient had a skin-to-capsule distance measurement greater than 3.5cm: (1)

b. Other *(specify):* (1)

_____

Skip to item 21.

12. Probe type used:

M: (1)

XL: (2)

D. FibroScan® exam #1 results

13. FibroScan® Technician PIN: ___ ___ ___

14. Number of valid measurements*: ___ ___
# of measurements

** Note: at least ten valid measurements should be made.*

15. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ ,___ ___
(1,5-75,0)

b. IQR (kPa): ___ ___ ,___ ___

c. IQR/med: ___ ___
%

16. Controlled Attenuation Parameter (CAP)
(skip if XL probe was used)

a. Median (dB/m): ___ ___ ___
(100-400)

b. IQR (dB/m): ___ ___ ___

E. FibroScan® exam #2 results

(This may be done by the same technician or a different technician).

17. FibroScan® Technician PIN: ___ ___ ___

18. Number of valid measurements*: ___ ___
# of measurements

** Note: at least ten valid measurements should be made.*

19. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ ,___ ___
(1,5-75,0)

b. IQR (kPa): ___ ___ ,___ ___

c. IQR/med: ___ ___
%

20. Controlled Attenuation Parameter (CAP)
(skip if XL probe was used)

a. Median (dB/m): ___ ___ ___
(100-400)

b. IQR (dB/m): ___ ___ ___

F. Administrative information

21. Study Physician PIN: ___ ___ ___

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ___ ___ ___

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

NAFLD Database 2

FR - FibroScan® Report

Purpose: To record key data from the FibroScan® exam.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: NASH CRN certified FibroScan® technician(s) and Study Physician.

IMPORTANT: **FibroScan® examinations may only be performed on NASH CRN patients. DO NOT perform on non-NASH CRN patients, per agreement with manufacturer.**

Instructions: Verify that the patient has understood and signed the FibroScan® consent form. Perform the exam per the procedures in the NAFLD Adult Database 2 SOP I. Briefly, this involves the following:
Before FibroScan® procedure, review the following basic information with patients: 1) Patients must have fasted for three or more hours prior to the FibroScan® procedure (necessary medications are allowed with small amounts of water). 2) Clothing must permit access to the abdomen.
Conduct of the two required FibroScan® procedures: 1) Obtain consent for the FibroScan® procedure. 2) Check that patient has no FibroScan® contraindications (see item 9). 3) Emphasize the need to remain still during the procedure. 4) On the FibroScan® device, enter the patient ID (e.g., 9999) in the Lastname field; enter the letter code (e.g., zyx) in the Firstname field, and enter the visit code followed by NASH in the Code field (e.g., t0 NASH). Enter NAFLD in the Admitting diagnosis field. Enter the PIN number of certified technician in the Operator field. 5) Position patient supine with right arm raised behind his/her head. 6) Apply a dime-sized amount of water based conduction gel over the liver. 7) Place M or XL probe over liver and obtain 10 valid measurements (if necessary, repeat until you have 10 valid measurements). 8) To choose between M and XL probe, follow the recommendation provided by the device. In case of recommendation fluctuating between M and XL, choose the XL. 9) Save test results, print test report, record results in Section D. 10) Repeat steps 5-9 above for second FibroScan® exam. 11) Record results from the second exam in Section E.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(date of FibroScan® exam):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: f r 3

7. Study: NAFLD Database 2 6

B. Consent

8. Has the patient signed the FibroScan® consent:

Yes (1) No (*2)

21.

** A FibroScan® exam should not be performed unless consent is obtained.*

9. Does the patient have any of the following contraindications *(check all that apply):*

a. An active implant such as pacemaker, defibrillator, pump, etc.: (1)

b. Wound near the site of scan: (1)

c. Pregnancy: (1)

d. Ascites (fluid in the abdomen): (1)

e. Patient did not fast for 3 hours: (1)

f. Were any of the items above (a-e) checked:

Yes (*1) No (2)

21.

** If any of the above are checked, the FibroScan® exam SHOULD NOT be performed. Skip to item 21.*

C. FibroScan® Procedure information

10. Was FibroScan® exam performed:

(Yes 1) (No * 2)

12.

** Complete item 11, then skip to item 21.*

11. Reason FibroScan® exam not performed *(check all that apply):*

a. Patient had a skin-to-capsule distance measurement greater than 3.5cm: (1)

b. Other *(specify):* (1)

_____

Skip to item 21.

12. Probe type used:

M: (1)

XL: (2)

D. FibroScan® exam #1 results

13. FibroScan® Technician PIN: ____ ____ ____

14. Number of valid measurements*: ____ ____
# of measurements

** Note: at least ten valid measurements should be made.*

15. Equivalent Liver Stiffness (E)

a. Median (kPa): ____ ____ __,__ ____
(1,5-75,0)

b. IQR (kPa): ____ ____ __,__ ____

c. IQR/med: ____ ____
%

16. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ____ ____ ____
(100-400)

E. FibroScan® exam #2 results

(This may be done by the same technician or a different technician).

17. FibroScan® Technician PIN: ____ ____ ____

18. Number of valid measurements*: ____ ____
# of measurements

** Note: at least ten valid measurements should be made.*

19. Equivalent Liver Stiffness (E)

a. Median (kPa): ____ ____ __,__ ____
(1,5-75,0)

b. IQR (kPa): ____ ____ __,__ ____

c. IQR/med: ____ ____
%

20. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ____ ____ ____
(100-400)

F. Administrative information

21. Study Physician PIN: ____ ____ ____

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ____ ____ ____

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

FR - FibroScan® Report

Purpose: To record key data from the FibroScan® exam.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: NASH CRN certified FibroScan® technician(s) and Study Physician.

IMPORTANT: **FibroScan® examinations may only be performed on NASH CRN patients. DO NOT perform on non-NASH CRN patients, per agreement with manufacturer.**

Instructions: Verify that the patient has understood and signed the FibroScan® consent form then file a copy in the patient records. Perform the exam per the procedures in the NAFLD Adult Database 2 SOP I. Briefly, this involves the following:

Before FibroScan® examination, review the following information with patients: 1) Patients must have fasted for three or more hours prior to the FibroScan® procedure (necessary medications are allowed with small amounts of water). 2) Clothing must permit access to the abdomen. 3) Check that the patient has no FibroScan® contraindications (see item 9).

Instructions for keying data on FibroScan Touch Screen

1) On the FibroScan® device, enter the patient ID (e.g., 9999) in the **LASTNAME** field; enter the letter code (e.g., zyx) in the **FIRSTNAME** field, and enter the visit code followed by NASH in the **CODE** field (e.g., t0 NASH). Enter NAFLD in the **ADMITTING DIAGNOSIS** field. Enter the PIN number of certified technician in the **OPERATOR** field.

Conduct of the two required FibroScan® procedures:

1) Emphasize the need to remain still during the procedure. 2) Position patient supine with right arm raised behind his/her head. 3) Apply a dime-sized amount of water based conduction gel over the liver. 4) Place M or XL probe over liver and obtain 10 valid measurements (if necessary, repeat until you have 10 valid measurements). 5) To choose between M and XL probe, follow the recommendation provided by the device. In case of recommendation fluctuating between M and XL, choose the XL. 6) Save test results, print test report, record results in Section D. 7) Repeat steps 2-6 above for second FibroScan® exam. Each patient will have two exams. Reminder: Exam #2 may be performed by the same technician who completed Exam #1 or by a different certified technician. 8) Record results from the second exam in Section E.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(date of FibroScan® exam):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: f r 4

7. Study: NAFLD Database 2 6

B. Consent

8. Has the patient signed the FibroScan® consent: Yes (1) No (*2)

21. ____

** A FibroScan® exam should not be performed unless consent is obtained.*

9. Does the patient have any of the following contraindications *(check all that apply):*

a. An active implant such as pacemaker, defibrillator, pump, etc.: (1)

b. Wound near the site of scan: (1)

c. Pregnancy: (1)

d. Ascites (fluid in the abdomen): (1)

e. Patient did not fast for 3 hours: (1)

f. Were any of the items above (a-e) checked: Yes (*1) No (2)

21. ____

** If any of the above are checked, the FibroScan® exam SHOULD NOT be performed. Skip to item 21.*

C. FibroScan® Procedure information

10. Was FibroScan® exam performed:

Yes (1) No (* 2)

12. ___

** Complete item 11, then skip to item 21.*

11. Reason FibroScan® exam not performed *(check all that apply):*

a. Patient had a skin-to-capsule distance measurement greater than 3.5cm: (1)

b. Other *(specify):* (1)

_____

Skip to item 21.

12. Probe type used:

M: (1)

XL: (2)

D. FibroScan® exam #1 results

13. FibroScan® Technician PIN: ___ ___ ___

14. Number of measurements

a. Valid measurements*: ___ ___
# of valid measurements

b. Invalid measurements: ___ ___
# of invalid measurements

To calculate invalid measurements subtract valid measurements from total measurements

** Note: at least ten valid measurements should be made.*

15. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ • ___
(1.5-75.0)

b. IQR (kPa): ___ ___ • ___

c. IQR/med: ___ ___
%

16. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ___ ___ ___
(100-400)

E. FibroScan® exam #2 results

(This may be done by the same technician or a different technician).

17. FibroScan® Technician PIN: ___ ___ ___

18. Number of measurements

a. Valid measurements*: ___ ___
# of valid measurements

b. Invalid measurements: ___ ___
# of invalid measurements

To calculate invalid measurements subtract valid measurements from total measurements

** Note: at least ten valid measurements should be made.*

19. Equivalent Liver Stiffness (E)

a. Median (kPa): ___ ___ • ___
(1.5-75.0)

b. IQR (kPa): ___ ___ • ___

c. IQR/med: ___ ___
%

20. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ___ ___ ___
(100-400)

F. Administrative information

21. Study Physician PIN: ___ ___ ___

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ___ ___ ___

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

___ ___ – ___ ___ – ___ ___
day mon year

NAFLD Database 2

FR - FibroScan® Report

Purpose: To record key data from the FibroScan® exam.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: NASH CRN certified FibroScan® technician(s) and Study Physician.

IMPORTANT: **FibroScan® examinations may only be performed on NASH CRN patients. DO NOT perform on non-NASH CRN patients, per agreement with manufacturer.**

Instructions: Verify that the patient has understood and signed the FibroScan® consent form then file a copy in the patient records. Perform the exam per the procedures in the NAFLD Adult Database 2 SOP I. Briefly, this involves the following:

Before FibroScan® examination, review the following information with patients: 1) Patients must have fasted for three or more hours prior to the FibroScan® procedure (necessary medications are allowed with small amounts of water). 2) Clothing must permit access to the abdomen. 3) Check that the patient has no FibroScan® contraindications (see item 9).

Instructions for keying data on FibroScan Touch Screen

1) On the FibroScan® device, enter the patient ID (e.g., 9999) in the **LASTNAME** field; enter the letter code (e.g., zyx) in the **FIRSTNAME** field, and enter the visit code followed by NASH in the **CODE** field (e.g., t0 NASH). Enter NAFLD in the **ADMITTING DIAGNOSIS** field. Enter the PIN number of certified technician in the **OPERATOR** field.

Conduct of the two required FibroScan® procedures:

1) Emphasize the need to remain still during the procedure. 2) Position patient supine with right arm raised behind his/her head. 3) Apply a dime-sized amount of water based conduction gel over the liver. 4) Place M or XL probe over liver and obtain 10 valid measurements (if necessary, repeat until you have 10 valid measurements). 5) To choose between M and XL probe, follow the recommendation provided by the device. In case of recommendation fluctuating between M and XL, choose the XL. 6) Save test results, print test report, record results in Section D. 7) Repeat steps 2-6 above for second FibroScan® exam. Each patient will have two exams. Reminder: Exam #2 may be performed by the same technician who completed Exam #1 or by a different certified technician. 8) Record results from the second exam in Section E.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(date of FibroScan® exam):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: f r 5

7. Study: NAFLD Database 2 6

B. Consent

8. Has the patient signed the FibroScan® consent:

Yes (1) No (*2)

21. ____

** A FibroScan® exam should not be performed unless consent is obtained.*

9. Does the patient have any of the following contraindications *(check all that apply):*

a. An active implant such as pacemaker, defibrillator, pump, etc.: (1)

b. Wound near the site of scan: (1)

c. Pregnancy: (1)

d. Ascites (fluid in the abdomen): (1)

e. Patient did not fast for 3 hours: (1)

f. Were any of the items above (a-e) checked:

Yes (*1) No (2)

21. ____

** If any of the above are checked, the FibroScan® exam SHOULD NOT be performed. Skip to item 21.*

C. FibroScan® Procedure information

10. Was FibroScan® exam performed:

Yes (1) No (* 2)

12.

** Complete item 11, then skip to item 21.*

11. Reason FibroScan® exam not performed *(check all that apply):*

a. Patient had a skin-to-capsule distance measurement greater than 3.5cm: (1)

b. Other *(specify):* (1)

_____

Skip to item 21.

12. Probe type used:

M: (1)

XL: (2)

D. FibroScan® exam #1 results

13. FibroScan® Technician PIN: ____ ____ ____

14. Number of measurements

a. Valid measurements*: ____ ____ # of valid measurements

b. Invalid measurements: ____ ____ # of invalid measurements

c. Total measurements: ____ ____ # of total measurements

To calculate invalid measurements, subtract valid measurements from total measurements

** Note: at least ten valid measurements should be made.*

15. Equivalent Liver Stiffness (E)

a. Median (kPa): ____ ____ ____ ____ (1.5-75.0)

b. IQR (kPa): ____ ____ ____ ____

c. IQR/med: ____ ____ %

16. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ____ ____ ____ (100-400)

b. IQR (dB/m): ____ ____ ____

E. FibroScan® exam #2 results

(This may be done by the same technician or a different technician).

17. FibroScan® Technician PIN: ____ ____ ____

18. Number of measurements

a. Valid measurements*: ____ ____ # of valid measurements

b. Invalid measurements: ____ ____ # of invalid measurements

c. Total measurements: ____ ____ # of total measurements

To calculate invalid measurements, subtract valid measurements from total measurements

** Note: at least ten valid measurements should be made.*

19. Equivalent Liver Stiffness (E)

a. Median (kPa): ____ ____ ____ ____ (1.5-75.0)

b. IQR (kPa): ____ ____ ____ ____

c. IQR/med: ____ ____ %

20. Controlled Attenuation Parameter (CAP)

a. Median (dB/m): ____ ____ ____ (100-400)

b. IQR (dB/m): ____ ____ ____

F. Administrative information

21. Study Physician PIN: ____ ____ ____

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ____ ____ ____

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____

day mon year

Keyed: ( )

NAFLD Database 2

HC - Hepatocellular Carcinoma Report

Purpose: To record the report of a patient's diagnosis of hepatocellular carcinoma (HCC).
When: As soon as clinic is notified of a patient's diagnosis of HCC.
Administered by: Study Physician and Clinical Coordinator.
Instructions: Complete and key this form whenever the clinical center is informed of a patient's diagnosis of HCC. Fax a copy of the Hepatocellular Carcinoma Report (HC) form to the DCC at (410) 955-0932; Attention: Pat Belt. Also, complete an Interim Event (IE) form to report a patient's HCC diagnosis in the NAFLD Database 2.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form initiated *(date of notice):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____ ____

6. Form & revision: h c 1

7. Study: NAFLD Database 2 6

B. Diagnosis information

8. Date of diagnosis:

____ ____–____ ____ ____–____ ____
day mon year

9. How was HCC identified *(check all that apply):*

a. Ultrasound: (1)
b. CT scan: (1)
c. MRI: (1)
d. Biopsy: (1)
e. Other *(specify):* (1)

_____

10. Were results of imaging obtained:

Yes (1) No (2)
15.

11. Were multiple tumors identified:

Yes (1) No (2)

12. Size of tumor *(enter size of largest tumor if more than one):*

____ ____ . ____
cm

13. Was early enhancement present:

Yes (1) No (2)

14. Was delayed washout present:

Yes (1) No (2)

15. Was serum marker alpha fetoprotein (AFP) obtained:

Yes (1) No (2)
16.

a. Was serum AFP elevated: Yes (1) No (2)

b. Serum AFP level:

____ , ____ ____ . ____
0.0 ng/mL - 2999.9 ng/mL

C. Administrative information

16. Study Physician PIN: ____ ____ ____

17. Study Physician signature:

_____

18. Clinical Coordinator PIN: ____ ____ ____

19. Clinical Coordinator signature:

_____

20. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

HI - Follow-up Medical History

Purpose: To record follow-up medical history information about the patient.
When: Visits t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient.
Instructions: Collect information by interview and chart review.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t____ ____ ____

6. Form & revision: h i 1

7. Study: NAFLD Database 2 6

B. Interval identification

8. Date of last Follow-up Medical History form *(if this is visit t048 then date of t0):*

____ ____–____ ____ ____–____ ____
day mon year

9. Visit code of last Follow-up Medical History form *(if this is visit t048 then t0):*

____ ____ ____ ____

C. NAFLD evaluation

10. Has the participant had a liver biopsy since the last visit:

(* Yes 1) (No 2)

**Complete the Liver Biopsy Materials Documentation (SD) form.*

11. Has the participant had an upper abdominal imaging study since the last visit:

(* Yes 1) (No 2)

**Complete a Liver Imaging Studies Report (IR) form.*

D. Alcohol consumption (AUDIT-C) since the last visit

12. Is the patient age 12 or older:

(Yes 1) (No 2)

19. ____

13. Since the last visit, how often have you had a drink containing alcohol:

Never (0)

16. ____

Monthly or less (1)
Two to four times a month (2)
Two to three times a week (3)
Four or more times a week (4)

14. Since the last visit, how many drinks containing alcohol have you had on a typical day when you are drinking:

1 or 2 (0)
3 or 4 (1)
5 or 6 (2)
7 to 9 (3)
10 or more (4)

15. Since the last visit, how often have you had six or more drinks on one occasion:

Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

E. Tobacco cigarette smoking

16. Since the last visit, have you smoked tobacco cigarettes regularly *("No" means smoked less than 1 day per week on average):*

Yes (1) No (2)

19. ____

17. On average, how many days per week have you smoked cigarettes: ____ # days

18. On the days that you smoked, about how many cigarettes did you smoke per day:

____ ____ ____ # cigarettes per day

F. Medical history

19. Since the last visit, has the patient been diagnosed with or treated for any of the following *(check all that apply; source of information can be interview and/or chart review)*

a. Diabetes type 1: (1)
b. Diabetes type 2: (1)
c. Gestational diabetes *(diabetes of pregnancy):* (1)
d. Hepatitis B: (1)
e. Hepatitis C: (1)
f. Autoimmune hepatitis: (1)
g. Autoimmune cholestatic liver disorder (PBC or PSC): (1)
h. Wilson's disease: (1)
i. Alpha-1-antitrypsin (A1AT) deficiency: (1)
j. Iron overload: (1)
k. Drug induced liver disease: (1)
l. Gilbert's syndrome: (1)
m. Esophageal or gastric varices on endoscopy: (1)
n. Bleeding from varices: (1)
o. Other gastrointestinal bleeding: (1)
p. Ascites: (1)
q. Edema: (1)
r. Hepatic encephalopathy: (1)
s. Portal hypertension: (1)
t. Hepatorenal syndrome: (1)
u. Hepatopulmonary syndrome: (1)
v. Short bowel syndrome: (1)
w. Hemophilia *(bleeding disorder):* (1)
x. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: (1)
y. Endocrine disease *(hormonal abnormality):* (1)
z. Hepatocellular carcinoma: (1)
aa. Other malignancy *(cancer):* (1)
ab. Peripheral neuropathy: (1)
ac. Seizure disorder or epilepsy: (1)
ad. Drug allergies: (1)
ae. Hypothyroidism: (1)
af. Hypertension: (1)
ag. Cerebrovascular disease: (1)
ah. Dysbetalipoproteinemia: (1)
ai. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)
aj. Pancreatitis: (1)
ak. Cholelithiasis: (1)
al. Coronary artery disease: (1)
am. Elevated uric acid such as gout: (1)
an. Kidney disease: (1)
ao. Polycystic ovary syndrome: (1)
ap. Sleep apnea *(not breathing during sleep):* (1)
aq. Dermatologic disorders: (1)
ar. Myopathy: (1)
as. Myositis: (1)
at. Major depression: (1)
au. Schizophrenia: (1)
av. Bipolar disorder: (1)
aw. Obsessive compulsive disorder: (1)
ax. Severe anxiety or personality disorder: (1)
ay. None of the above: (1)

20. Since the last visit, has the patient had surgery for any of the following *(check all that apply)*

a. Stapling or banding of the stomach: (1)
b. Jejunoileal *(or other intestinal)* bypass: (1)
c. Biliopancreatic diversion: (1)
d. Other GI or bariatric surgery *(specify):* (1)

_____

e. None: (1)

21. Since the last visit, has the patient received an organ, limb, or bone marrow transplant:

Yes (1) No (2)

22. Since the last visit, has the patient received total parenteral nutrition (TPN):

Yes (1) No (2)

23. Is the patient currently undergoing evaluation for bariatric surgery:

Yes (1) No (2)

24. Since the last visit, has the patient been hospitalized:

Yes (1) No (2)
25.

If Yes, specify reason:

_____
specify reason

25. Since the last visit, has the patient had any serious health problem not already reported:

Yes (1) No (2)
26.

If Yes, specify:

_____
specify

G. Medication use

26. Since the last visit, has the patient used any antidiabetic medications *(If yes, check all that apply)*

Yes (1) No (2)
27.

a. Acarbose (Precose): (1)
b. Acetohexamide (Dymelor): (1)
c. Chlorpropamide (Diabinese): (1)
d. Glimepiride (Amaryl): (1)
e. Glipizide (Glucotrol, Glucatrol XL): (1)
f. Glyburide (Micronase, DiaBeta, Glynase): (1)
g. Insulin: (1)
h. Metformin (Glucophage, Glucophage XR): (1)
i. Miglitol (Glycet): (1)
j. Nateglinide (Starlix): (1)
k. Pioglitazone (Actos): (1)
l. Repaglinide (Prandin): (1)
m. Rosiglitazone (Avandia): (1)
n. Tolazamide (Tolinase): (1)
o. Tolbutamide (Orinase): (1)
p. Other, *(specify):* (1)

_____

27. Since the last visit, has the patient taken any alcohol abuse (dependance or withdrawal) medications:

Yes (1) No (2)

28. Since the last visit, has the patient taken any antihyperlipidemic medications *(If yes, check all that apply)*

Yes (1) No (2)

29.

a. Atorvastatin (Lipitor): (1)
b. Colestipol hydrochloride (Colestid): (1)
c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (1)
d. Gemfibrozil (Gen-Fibro, Lopid): (1)
e. Fenofibrate (Tricor): (1)
f. Fluvastatin sodium (Lescol): (1)
g. Lovastatin (Mevacor): (1)
h. Nicotinic acid (Niaspan): (1)
i. Pravastatin sodium (Pravachol): (1)
j. Rosuvastatin (Crestor): (1)
k. Simvastatin (Zocor): (1)
l. Other, *(specify):* (1)

_____

29. Since the last visit, has the patient taken any antiobesity medications:

Yes (1) No (2)

30. Since the last visit, has the patient taken any systemic corticosteroids:

Yes (1) No (2)

31. Since the last visit, has the patient taken any cardiovascular/antihypertensive medications *(If yes, check all that apply)*

Yes (1) No (2)

32.

a. Amiodarone (Pacerone): (1)
b. Amlodipine besylate (Norvasc): (1)
c. Atenolol (Tenormin): (1)
d. Benazepril (Lotensin): (1)
e. Captopril (Capoten): (1)
f. Clonidine (Catapres): (1)
g. Digoxin (Lanoxin): (1)
h. Diltiazem (Cardizem): (1)
i. Doxazosin (Cardura): (1)
j. Enalapril (Vasotec): (1)
k. Felodipine (Plendil): (1)
l. Furosemide (Lasix): (1)
m. Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)
n. Hydrochlorothiazide + triamterene (Dyazide): (1)
o. Lisinopril (Prinivil, Zestril): (1)
p. Losartan potassium (Cozaar): (1)
q. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)
r. Metoprolol (Lopressor): (1)
s. Nifedipine (Adalat, Procardia): (1)
t. Perhexiline maleate: (1)
u. Propranolol (Inderal): (1)
v. Quinapril (Accupril): (1)
w. Terazosin (Hytrin): (1)
x. Timolol maleate (Blocadren): (1)
y. Valsartan (Diovan): (1)
z. Verapamil (Calan): (1)
aa. Other, *(specify):* (1)

_____

ab. Other, *(specify):* (1)

_____

32. Since the last visit, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators *(If yes, check all that apply)*

	Yes (1)	No (2)
a. Oral contraceptives:	(1)	
b. Raloxifene (Evista):	(1)	
c. Tamoxifen (Nolvadex):	(1)	
d. Other, *(specify):*	(1)	

33.

_____

33. Since the last visit, has patient taken any of the following vitamins or supplements *(If yes, check all that apply)*

	Yes (1)	No (2)
		34.
a. MultiVitamin:	(1)	
b. Vitamin B (any type):	(1)	
c. Vitamin C:	(1)	
d. Vitamin D:	(1)	
e. Vitamin E:	(1)	
f. Alpha-lipoic acid:	(1)	
g. Alpha-tocopherol:	(1)	
h. Beta-carotene:	(1)	
i. Betaine (Cystadane):	(1)	
j. Calcium (any form):	(1)	
k. Carnitine (any form):	(1)	
l. Choline + methionine + betaine + adenosine + pyridoxine (Epocler):	(1)	
m. Cod liver oil:	(1)	
n. Coenzyme Q:	(1)	
o. Echinacea:	(1)	
p. Fish oil (any form):	(1)	
q. Flax seed oil:	(1)	
r. Garlic:	(1)	
s. Ginkgo biloba:	(1)	
t. Glucosamine (any form):	(1)	
u. Lecithin:	(1)	
v. Milk thistle:	(1)	
w. N-acetyl-cysteine:	(1)	
x. S-adenylmethionine (SAM-e):	(1)	
y. Saw palmetto:	(1)	
z. Selenium:	(1)	
aa. St. John's Wort:	(1)	
ab. Taurine:	(1)	
ac. Zinc picolinate:	(1)	
ad. Other, *(specify):*	(1)	

_____

34. Since the last visit, has patient taken any of the following medications or other supplements/medications *(If yes, check all that apply)*

	Yes (1)	No (2)
		35.
a. Demeclocycline (Declomycin):	(1)	
b. Divalproex (Depakote):	(1)	
c. Doxycycline (Monodox):	(1)	
d. Isotretinoin (Accutane):	(1)	
e. Levothyroxine (Levoxyl, Synthroid):	(1)	
f. Liothyronine (Cytomel):	(1)	
g. Methotrexate (Rheumatrex):	(1)	
h. Minocycline (Dynacin, Minocin):	(1)	
i. Oxytetracycline (Terramycin):	(1)	
j. Tetracycline (Achromycin):	(1)	
k. Ursodeoxycholic acid (Actigall, Urso, Ursodiol):	(1)	
l. Valproate sodium (Depacon):	(1)	
m. Valproic acid (Depakene):	(1)	
n. Other, *(specify):*	(1)	
_____		
o. Other, *(specify):*	(1)	
_____		

35. Since the last visit, has patient taken any pain relieving, non-steroidal anti-inflammatory, aspirin, or acetaminophen-containing medications:

	Yes (1)	No (2)
	(1)	(2)

H. Summary judgments about specific liver conditions *(these judgments are to be made after all of the visit data are collected)*

36. Subscores to compute Child-Pugh Turcotte score

a. Rate the patient's ascites *(check only one):*

None	(1)
Mild, easily managed	(2)
Severe, refractory	(3)

b. Rate the patient's hepatic encephalopathy *(check only one):*

None	(1)
Mild, easily managed	(2)
Severe, refractory	(3)

I. Administrative information

37. Study Physician PIN: ____ ____ ____

38. Study Physician signature:

_____

39. Clinical Coordinator PIN: ____ ____ ____

40. Clinical Coordinator signature:

_____

41. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

NAFLD Database 2

IE - Interim Event Report

Purpose: To document (1) events that occur after registration but before enrollment, or between regular follow-up visits, that impact on the patient's participation in the NAFLD Database 2 Study (eg, mild or moderate liver biopsy complications), or (2) other event that clinical center staff feel should be reported now rather than wait until the next follow-up visit and that is not recorded on another NAFLD Database 2 form.

When: As needed; use visit code n. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code n for first event, n1 for second event, etc.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at www.nashcrn.com. Click on Documents and then click on General Documents. Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).

NASH CRN Data Coordinating Center telephone number: (410) 955-8175.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____ ____

6. Form & revision: i e 1

7. Study: NAFLD Database 2 6

B. Visit interval identification

8. Most recently completed visit (screening or follow-up)

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Visit code:

____ ____ ____ ____

C. Patient information

9. Date enrolled in NAFLD Database 2 Study *(enter n if patient is not yet enrolled):*

____ ____–____ ____ ____–____ ____
day mon year

10. Gender:

Male (1)
Female (2)

11. Age at time of event: ____ ____ years

D. Event description

12. Date event started:

____ ____–____ ____ ____–____ ____
day mon year

13. Nature of event *(check all that apply)*

a. General anesthesia (1)
b. Study procedure related event: (1)
c. Drug interactions: (1)
d. Worsening of a co-morbid illness: (1)
e. Hypoglycemia: (1)
f. New-onset diabetes: (1)
g. Pregnancy *(patient):* (1)
h. Other *(specify):* (1)

_____

_____

14. Did the event lead to *(check all that apply)*

a. Emergency room visit: (1)
b. Hospitalization: (1)
c. Infectious episode: (1)
d. Surgical intervention: (1)

15. Describe event:

16. Short name for event if applicable *(short names for AEs are listed in the CTCAE v3.0 document available at www.nashcrn.com; click on Documents and then click on General Documents):*

Not applicable (0)

17. Severity grade *(severity grades are listed in the CTCAE v3.0 document available at www.nashcrn.com; click on Documents and then click on General Documents):*

Not applicable	(0)
Grade 1 - Mild	(1)
Grade 2 - Moderate	(2)
Grade 3 - Severe	(3)
Grade 4 - Life threatening or disabling	(4)
Grade 5 - Death	(*5)

**Complete and key Death Report (DR) form.*

18. Date event resolved *(enter n if event is not yet resolved):*

____ ____–____ ____ ____–____ ____
day mon year

19. What action was taken:

20. Other comments on event:

F. Administrative information

21. Clinical Coordinator PIN: ____ ____ ____

22. Clinical Coordinator signature:

23. Study Physician PIN: ____ ____ ____

24. Study Physician signature:

25. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.

NAFLD Database 2

IE - Interim Event Report

Purpose: To document events that occur after registration that impact on the patient's participation in the NAFLD Database 2 Study (eg, mild or moderate liver biopsy complications). Complete this form if there has been an incident cirrhosis, hepatocellular carcinoma (HCC), hospitalization, Emergency Room visit, liver transplant, an event associated with a study-related procedure, or death.

When: As needed; use visit code n. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code n for first event, n1 for second event, etc.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at https://jhuccs1.us/nash/default.asp. Click on Documents and then click on General Documents. **Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).**

NASH CRN Data Coordinating Center telephone number: (410) 955-8175.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code:

n ____ ____ ____

6. Form & revision: i e 2

7. Study: NAFLD Database 2 6

B. Visit interval identification

8. Most recently completed visit (screening or follow-up)

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Visit code: ____ ____ ____ ____

C. Patient information

9. Date enrolled in NAFLD Database 2 Study *(enter n if patient is not yet enrolled):*

____ ____–____ ____ ____–____ ____
day mon year

10. Gender:

Male (1)
Female (2)

11. Age at time of event: ____ ____ years

D. Event description

12. Date event started:

____ ____–____ ____ ____–____ ____
day mon year

13. Nature of event *(check all that apply)*

a. General anesthesia (1)
b. Study-related procedure: (1)
c. Drug interactions: (1)
d. Worsening of a co-morbid illness: (1)
e. Hypoglycemia: (1)
f. New-onset diabetes: (1)
g. Pregnancy *(patient):* (1)
h. Cirrhosis: (1)
i. Hepatocellular carcinoma (HCC): (* 1)
** Complete and key the HC form.*
j. Other *(specify):* (1)

_____

_____

14. Did the event lead to *(check all that apply)*

a. Emergency room visit: (1)

b. Hospitalization: (1)

c. Infectious episode: (1)

d. Surgical intervention: (1)

15. Describe event:

16. Indicate the name for the event obtained from the NCI's Common Terminology Criteria for Adverse Events *(CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp; click on Documents and then click on General Documents):*

a. Not in CTCAE (e.g. malignancy, data breach) *(specify):* (1)

17. Indicate the severity code using the CTCAE grading scale for the AE specified *(severity grades are listed in the CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp; click on Documents and then click on General Documents):*

Grade 1 - Mild	(1)
Grade 2 - Moderate	(2)
Grade 3 - Severe†	(3)
Grade 4 - Life threatening or disabling†	(4)
Grade 5 - Death†	(* 5)

†Fax the DCC (Attention Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).

**Complete and key Death Report (DR) form.*

18. Date event resolved *(enter n if event is not yet resolved):*

____ ____–____ ____ ____–____ ____
day mon year

19. What action was taken:

20. Other comments on event:

F. Administrative information

21. Clinical Coordinator PIN: ____ ____ ____

22. Clinical Coordinator signature:

23. Study Physician PIN: ____ ____ ____

24. Study Physician signature:

25. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.

NAFLD Database 2

IE - Interim Event Report

Purpose: To document events that occur after registration that impact on the patient's participation in the NAFLD Database 2 Study (eg, mild or moderate liver biopsy complications). Complete this form if there has been an incident cirrhosis, hepatocellular carcinoma (HCC), hospitalization, Emergency Room visit, liver transplant, an event associated with a study-related procedure, or death.

When: As needed; use visit code n. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code n for first event, n1 for second event, etc.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at https://jhuccs1.us/nash/default.asp. Click on Documents and then click on General Documents. **Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).**

NASH CRN Data Coordinating Center telephone number: (410) 955-8175.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code:

n ____ ____ ____

6. Form & revision: i e 3

7. Study: NAFLD Database 2 6

B. Visit interval identification

8. Most recently completed visit (screening or follow-up)

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Visit code: ____ ____ ____ ____

C. Patient information

9. Date enrolled in NAFLD Database 2 Study *(enter n if patient is not yet enrolled):*

____ ____–____ ____ ____–____ ____
day mon year

10. Gender:

Male (1)
Female (2)

11. Age at time of event: ____ ____
years

D. Event description

12. Date event started:

____ ____–____ ____ ____–____ ____
day mon year

13. Nature of event *(check all that apply)*

a. General anesthesia (1)
b. Study-related procedure: (1)
c. Drug interactions: (1)
d. Worsening of a co-morbid illness: (1)
e. Hypoglycemia: (1)
f. New-onset diabetes: (1)
g. Pregnancy *(patient):* (1)
h. Cirrhosis: (1)
i. Hepatocellular carcinoma (HCC): (* 1)
** Complete and key the HC form.*
j. Other *(specify):* (1)

_____

_____

14. Did the event lead to *(check all that apply)*

a. Emergency room visit: (1)

b. Hospitalization: (1)

c. Infectious episode: (1)

d. Surgical intervention: (1)

15. Describe event:

16. Is the event listed in the NCIs Common Terminology Criteria for Adverse Events (*CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp; click on Documents and then click on General Documents*):

Yes (1) No (2)

a. Indicate the name of the event (if in the CTCAE, specify name exactly from document; if not in CTCAE specify name):

17. Indicate the severity code using the CTCAE grading scale for the AE specified (*severity grades are listed in the CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp; click on Documents and then click on General Documents*):

Grade 1 - Mild (1)

Grade 2 - Moderate (2)

Grade 3 - Severe† (3)

Grade 4 - Life threatening or disabling† (4)

Grade 5 - Death† (* 5)

†*Fax the DCC (Attention Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).*

**Complete and key Death Report (DR) form.*

18. Date event resolved
(enter n if event is not yet resolved):

____ ____–____ ____ ____–____ ____
day mon year

19. What action was taken:

20. Other comments on event:

F. Administrative information

21. Clinical Coordinator PIN: ____ ____ ____

22. Clinical Coordinator signature:

23. Study Physician PIN: ____ ____ ____

24. Study Physician signature:

25. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.

NAFLD Database 2

IR - Liver Imaging Studies Report

Purpose: To record liver imaging study results.

When: As needed during screening (visit t0) and follow-up (visits t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480).

Administered by: Clinical Coordinator.

Instructions: Complete this form at each of the visits listed above if the Baseline Medical History (BG) or Follow-up Medical History (HI) form says that a liver imaging study was obtained in the specified period. The form will allow you to skip out of sections that are irrelevant to your patient. What you will report at each visit are the results of the most recent scan of each type done in the 6 months prior to screening (visit t0) or in the period since the prior study visit (after enrollment). These will likely be standard of care scans with results obtained via medical records. In each case, answer the items based on review of the report; the Study Physician must review and approve the findings recorded on this form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: i r 1

7. Study: NAFLD Database 2 6

B. Upper abdominal ultrasound

8. Did the patient have an upper abdominal ultrasound in the past 6 months *(screening)*/since the last visit *(follow-up)*:

Yes (1) No (2)

11.

9. Date of most recent upper abdominal ultrasound:

____ ____–____ ____ ____–____ ____
day mon year

10. Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance *(check all that apply)*

a. Fatty infiltration: (1)

b. Cirrhosis: (1)

c. Hepatomegaly: (1)

d. Hepatic mass: (1)

e. Intrahepatic biliary dilatation: (1)

f. Extrahepatic biliary dilatation: (1)

g. Gallstones/cholelithiasis: (1)

h. Gall bladder polyps: (1)

i. Cholecystectomy: (1)

j. Splenomegaly: (1)

k. Ascites: (1)

l. Other features of portal hypertension *(specify):* (1)

_____

_____

m. Other abnormality *(specify):* (1)

_____

_____

n. None of the above: (1)

C. Upper abdominal CT scan

11. Did the patient have an upper abdominal CT scan in the past 6 months *(screening)*/ since the last visit *(follow-up)*:

Yes (1) No (2)

→ **14.**

12. Date of most recent upper abdominal CT scan:

____ ____–____ ____ ____–____ ____
day mon year

13. Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance *(check all that apply)*

- **a.** Fatty infiltration: (1)
- **b.** Cirrhosis: (1)
- **c.** Hepatomegaly: (1)
- **d.** Hepatic mass: (1)
- **e.** Hepatic hemangioma: (1)
- **f.** Hepatic cyst: (1)
- **g.** Intrahepatic biliary dilatation: (1)
- **h.** Extrahepatic biliary dilatation: (1)
- **i.** Gallstones/cholelithiasis: (1)
- **j.** Gall bladder polyps: (1)
- **k.** Cholecystectomy: (1)
- **l.** Splenomegaly: (1)
- **m.** Ascites: (1)
- **n.** Other features of portal hypertension *(specify):* (1)

  _____

  _____

- **o.** Other abnormality *(specify):* (1)

  _____

  _____

- **p.** None of the above: (1)

D. Upper abdominal MRI

14. Did the patient have an upper abdominal MRI in the past 6 months *(screening)*/ since the last visit *(follow-up)*:

Yes (1) No (2)

→ **17.**

15. Date of most recent upper abdominal MRI:

____ ____–____ ____ ____–____ ____
day mon year

16. Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance *(check all that apply)*

- **a.** Fatty infiltration: (1)
- **b.** Cirrhosis: (1)
- **c.** Hepatomegaly: (1)
- **d.** Hepatic mass: (1)
- **e.** Hepatic hemangioma: (1)
- **f.** Hepatic cyst: (1)
- **g.** Intrahepatic biliary dilatation: (1)
- **h.** Extrahepatic biliary dilatation: (1)
- **i.** Splenomegaly: (1)
- **j.** Ascites: (1)
- **k.** Other features of portal hypertension *(specify):* (1)

  _____

  _____

- **l.** Other abnormality *(specify):* (1)

  _____

  _____

- **m.** None of the above: (1)

E. Administrative information

17. Study Physician PIN: ____ ____ ____

18. Study Physician signature:

_____

19. Clinical Coordinator PIN: ____ ____ ____

20. Clinical Coordinator signature:

_____

21. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

LD – Lifetime Drinking History (Skinner)

Purpose: To obtain quantitative indices of the patient's alcohol consumption patterns from the onset of regular drinking.
When: Visit t0. If more than one LD form is needed, use visit code "n" on the second LD form.
Administered by: Clinical Coordinator.
Respondent: New Database 2 Patients, 18 years of age or older, without help from spouse or family.
Instructions: <u>Complete this form for new Database 2 patients only.</u> In addition to actual consumption levels (quantity), attention is focused upon the frequency of use, variability in consumption, types of beverages, life events that mark a change in drinking pattern, solitary versus social drinking, and time of day when alcohol is consumed. Flash Card #9, Drink Equivalents, may be used with this interview.

The interviewer begins by recording the patient's alcohol consumption behavior during the first year that he/she drank on a regular basis (at least one drink per month). Then, the patient is asked to think of when his/her drinking behavior changed in any appreciable way. In a chronological fashion, the interviewer traces the patient's alcohol consumption behavior from the age of first regular drinking to the present. Flash Card #10, Patterns of Alcohol Intake, provides sample language for the interviewer. Each LD form allows for describing six drinking phases. Use a second LD form (visit code "n") if needed to describe additional drinking phases. If this is the second LD form, skip sections B and C and start with item 20.

The interview takes approximately 20 minutes to complete. It is best given after a reasonable degree of rapport has been established, whereby the patient will feel more at ease and talk openly. Other, considerable probing and cross-referencing of facts is necessary to help in accurate recall. All information should be recorded under the appropriate heading on the LD form.

A. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit *(date patient completed the form)*:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

5. Visit code: _____ _____ _____ _____

6. Form & revision: **l d 1**

7. Study: NAFLD Database 2 6

B. Lifetime alcohol consumption

8. Over the course of your lifetime have you ever had at least one drink of alcohol, beer, liquor, wine, or wine coolers, per month during a 12-month time period, or at least three drinks per day for at least three consecutive days (over a regular period of time):

Yes (1) No (2)

81. ◄

C. First phase

Read as written: *"Now, I am going to ask you about your drinking pattern during the first year that you began to have at least one drink per month until your drinking behavior was different in a significant way from this time."*

9. How old were you when you began regular drinking:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

10. How old were you at the end of first stage:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

11. During the first stage, how many drinks would you have on average per occasion *(drinking day)*:

____ ____ # drinks

12. How many days per month would you generally drink at this level:

____ ____ # days

13. What is the most or maximum number of drinks you would have in any one day:

____ ____ # drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

14. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%)*:

Beer ____ ____ ____ %

Liquor ____ ____ ____ %

Wine ____ ____ ____ %

15. How would you rate your usual style of drinking during an average month *(check the appropriate category)*;

Abstinent	(1)
Occasional *(less than 15 days)*	(2)
Weekend mainly	(3)
Binge *(at least 3 days heavy drinking)*	(4)
Frequent *(15 days or more per month)*	(5)

16. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2)

18. ◀

17. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

		Positive	Negative	Neutral
a.	Marital/family . .	(1)	(2)	(3)
b.	Work	(1)	(2)	(3)
c.	School	(1)	(2)	(3)
d.	Medical	(1)	(2)	(3)
e.	Residence	(1)	(2)	(3)
f.	Legal/jail	(1)	(2)	(3)
g.	Financial	(1)	(2)	(3)
h.	Peer group	(1)	(2)	(3)
i.	Drug abuse	(1)	(2)	(3)
j.	Treatment	(1)	(2)	(3)
k.	Death	(1)	(2)	(3)
l.	Emotional	(1)	(2)	(3)

18. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%):*

Alone ____ ____ ____ %

With others ____ ____ ____ %

19. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ ____ %

Afternoon ____ ____ ____ %

Evening ____ ____ ____ %

D. Subsequent phase

20. **Read as written**: "We have just discussed your drinking habits at the point when you first began to drink regularly. Now I want you to think to when your drinking behavior was different in a significant way from this time. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits":

Yes (1) No (2)

81.

21. How old were you at the beginning of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

22. How old were you at the end of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

23. During this phase, how many drinks would you have on average per occasion *(drinking day)*:

____ ____ # drinks

24. How many days per month would you generally drink at this level *(write "m" if not drinking)*:

____ ____ # days

25. What is the most or maximum number of drinks you would have in any one day:

____ ____ # drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

26. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Beer ____ ____ ____ %

Liquor ____ ____ ____ %

Wine ____ ____ ____ %

27. How would you rate your usual style of drinking during an average month *(check the appropriate category)*:

Abstinent	(1)
Occasional *(less than 15 days)*	(2)
Weekend mainly	(3)
Binge *(at least 3 days heavy drinking)*	(4)
Frequent *(15 days or more per month)*	(5)

28. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2)

30.

29. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

	Positive	Negative	Neutral
a. Marital/family . .	(1)	(2)	(3)
b. Work	(1)	(2)	(3)
c. School	(1)	(2)	(3)
d. Medical	(1)	(2)	(3)
e. Residence	(1)	(2)	(3)
f. Legal/jail	(1)	(2)	(3)
g. Financial	(1)	(2)	(3)
h. Peer group	(1)	(2)	(3)
i. Drug abuse	(1)	(2)	(3)
j. Treatment	(1)	(2)	(3)
k. Death	(1)	(2)	(3)
l. Emotional	(1)	(2)	(3)

30. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):*

Alone ____ ____ ____ %

With others ____ ____ ____ %

31. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ ____ %

Afternoon ____ ____ ____ %

Evening ____ ____ ____ %

E. Next subsequent phase

32. **Read as written**: "We have just discussed your drinking habits when you first began to drink regularly and at a subsequent phase. Now I want you to think to when your drinking behavior was different in a significant way from the previous phase. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits":

Yes (1) No (2)

81. ◄

33. How old were you at the beginning of the phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

34. How old were you at the end of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

35. During this phase, how many drinks would you have on average per occasion *(drinking day)*:

____ ____ # drinks

36. How many days per month would you generally drink at this level *(write "m" if not drinking)*:

____ ____ # days

37. What is the most or maximum number of drinks you would have in any one day:

____ ____ # drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

38. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Beer ____ ____ ____ %

Liquor ____ ____ ____ %

Wine ____ ____ ____ %

39. How would you rate your usual style of drinking during an average month *(check the appropriate category)*;

Abstinent	(1)
Occasional *(less than 15 days)*	(2)
Weekend mainly	(3)
Binge *(at least 3 days heavy drinking)*	(4)
Frequent *(15 days or more per month)*	(5)

40. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2)

→ **42.**

41. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

		Positive	Negative	Neutral
a.	Marital/family . .	(1)	(2)	(3)
b.	Work	(1)	(2)	(3)
c.	School	(1)	(2)	(3)
d.	Medical	(1)	(2)	(3)
e.	Residence	(1)	(2)	(3)
f.	Legal/jail	(1)	(2)	(3)
g.	Financial	(1)	(2)	(3)
h.	Peer group	(1)	(2)	(3)
i.	Drug abuse	(1)	(2)	(3)
j.	Treatment	(1)	(2)	(3)
k.	Death	(1)	(2)	(3)
l.	Emotional	(1)	(2)	(3)

42. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):*

Alone ____ ____ ____ %

With others ____ ____ ____ %

43. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ ____ %

Afternoon ____ ____ ____ %

Evening ____ ____ ____ %

F. Next subsequent phase

44. **Read as written**: "We have just discussed your drinking habits when you first began to drink regularly and at subsequent phases. Now I want you to think to when your drinking behavior was different in a significant way from the previous phase. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits":

Yes (1) No (2)

→ **81.**

45. How old were you at the beginning of the phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

46. How old were you at the end of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

47. During this phase, how many drinks would you have on average per occasion *(drinking day)*:

____ ____ # drinks

48. How many days per month would you generally drink at this level *(write "m" if not drinking)*:

____ ____ # days

49. What is the most or maximum number of drinks you would have in any one day:

____ ____ # drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

50. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Beer ____ ____ % ____

Liquor ____ ____ % ____

Wine ____ ____ % ____

51. How would you rate your usual style of drinking during an average month *(check the appropriate category)*;

Abstinent (1)
Occasional *(less than 15 days)* (2)
Weekend mainly (3)
Binge *(at least 3 days heavy drinking)* (4)
Frequent *(15 days or more per month)* (5)

52. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2) → **54.**

53. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

		Positive	Negative	Neutral
a.	Marital/family . .	(1)	(2)	(3)
b.	Work	(1)	(2)	(3)
c.	School	(1)	(2)	(3)
d.	Medical	(1)	(2)	(3)
e.	Residence	(1)	(2)	(3)
f.	Legal/jail	(1)	(2)	(3)
g.	Financial	(1)	(2)	(3)
h.	Peer group	(1)	(2)	(3)
i.	Drug abuse	(1)	(2)	(3)
j.	Treatment	(1)	(2)	(3)
k.	Death	(1)	(2)	(3)
l.	Emotional	(1)	(2)	(3)

54. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):*

Alone ____ ____ % ____

With others ____ ____ % ____

55. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ % ____

Afternoon ____ ____ % ____

Evening ____ ____ % ____

G. Next subsequent phase

56. **Read as written**: *"We have just discussed your drinking habits when you first began to drink regularly and at subsequent phases. Now I want you to think to when your drinking behavior was different in a significant way from the previous phase. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits"*:

Yes (1) No (2) → **81.**

57. How old were you at the beginning of the phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

58. How old were you at the end of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

59. During this phase, how many drinks would you have on average per occasion *(drinking day)*:

____ ____
drinks

60. How many days per month would you generally drink at this level *(write "m" if not drinking)*:

____ ____
days

61. What is the most or maximum number of drinks you would have in any one day:

____ ____
drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

62. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Beer ____ ____ ____ %

Liquor ____ ____ ____ %

Wine ____ ____ ____ %

63. How would you rate your usual style of drinking during an average month *(check the appropriate category)*;

Abstinent	(1)
Occasional *(less than 15 days)*	(2)
Weekend mainly	(3)
Binge *(at least 3 days heavy drinking)*	(4)
Frequent *(15 days or more per month)*	(5)

64. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2)

66.

65. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

		Positive	Negative	Neutral
a.	Marital/family . .	(1)	(2)	(3)
b.	Work	(1)	(2)	(3)
c.	School	(1)	(2)	(3)
d.	Medical	(1)	(2)	(3)
e.	Residence	(1)	(2)	(3)
f.	Legal/jail	(1)	(2)	(3)
g.	Financial	(1)	(2)	(3)
h.	Peer group	(1)	(2)	(3)
i.	Drug abuse	(1)	(2)	(3)
j.	Treatment	(1)	(2)	(3)
k.	Death	(1)	(2)	(3)
l.	Emotional	(1)	(2)	(3)

66. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):*

Alone ____ ____ ____ %

With others ____ ____ ____ %

67. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ ____ %

Afternoon ____ ____ ____ %

Evening ____ ____ ____ %

H. Next subsequent phase

68. **Read as written**: "We have just discussed your drinking habits when you first began to drink regularly and at subsequent phases. Now I want you to think to when your drinking behavior was different in a significant way from the previous phase. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits":

Yes (1) No (2)

→ **81.**

69. How old were you at the beginning of the phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

70. How old were you at the end of this phase:

a. Years: ____ ____ yrs

b. Months: ____ ____ mos

71. During this phase, how many drinks would you have on average per occasion *(drinking day)*:

____ ____ # drinks

72. How many days per month would you generally drink at this level *(write "m" if not drinking)*:

____ ____ # days

73. What is the most or maximum number of drinks you would have in any one day:

____ ____ # drinks

(*Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.*)

74. What type of beverage would you usually consume in an average month *(record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Beer ____ ____ ____ %

Liquor ____ ____ ____ %

Wine ____ ____ ____ %

75. How would you rate your usual style of drinking during an average month *(check the appropriate category)*;

Abstinent	(1)
Occasional *(less than 15 days)*	(2)
Weekend mainly	(3)
Binge *(at least 3 days heavy drinking)*	(4)
Frequent *(15 days or more per month)*	(5)

76. Did any important event or events occur during this period that altered your usual drinking habits:

Yes (1) No (2)

→ **78.**

77. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life *(for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect)*:

		Positive	Negative	Neutral
a.	Marital/family . .	(1)	(2)	(3)
b.	Work	(1)	(2)	(3)
c.	School	(1)	(2)	(3)
d.	Medical	(1)	(2)	(3)
e.	Residence	(1)	(2)	(3)
f.	Legal/jail	(1)	(2)	(3)
g.	Financial	(1)	(2)	(3)
h.	Peer group	(1)	(2)	(3)
i.	Drug abuse	(1)	(2)	(3)
j.	Treatment	(1)	(2)	(3)
k.	Death	(1)	(2)	(3)
l.	Emotional	(1)	(2)	(3)

78. What percentage of time would you drink alone, and what percentage of the time with at least one other person *(record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should all be "000"):*

Alone ____ ____ ____ %

With others ____ ____ ____ %

79. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning *(record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000")*:

Morning ____ ____ ____ %

Afternoon ____ ____ ____ %

Evening ____ ____ ____ %

I. Number of phases

80. Are there any additional subsequent phases:

Yes (* 1) No (2)

** If yes, complete a second LD form.*
Skip sections B and C on second form.

J. Administrative information

81. Clinical Coordinator PIN: ____ ____ ____

82. Clinical Coordinator signature:

_____

83. Date form reviewed:

____ ____ - ____ ____ ____ - ____ ____
day mon year

NAFLD Database 2

LR - Laboratory Results - Tests Done During Screening and Follow-up

Purpose: To record archival and current laboratory test results for tests done during both screening and follow-up.
When: Visits t0, t048, t096, t144, and t192.
Administered by: Study Physician and Clinical Coordinator.
Instructions: All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit *(date form was initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t ____ ____ ____

6. Form & revision: 1 r 1

7. Study: NAFLD Database 2 6

B. Hematology

8. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. Mean corpuscular volume (MCV):

____ ____ ____
fL

12. White blood cell count (WBC):

____ ____ ____ • ____ ____
10^3 cells/µL or 10^9 cells/L

13. Platelet count:

____,____ ____ ____,____ ____ ____
cells/µL

C. Chemistries and HbA1c

14. Date of blood draw for chemistries:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

15. Blood urea nitrogen (BUN): ____ ____
mg/dL

16. Creatinine: ____ ____ • ____ ____
mg/dL

17. Uric acid: ____ ____ • ____ ____
mg/dL

18. Date of blood draw for HbA1c:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

19. HbA1c: ____ ____ • ____ ____
%

D. Liver panel

20. Date of blood draw for liver panel:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

21. Bilirubin (total): ____ ____ • ____ ____ mg/dL

22. Bilirubin (direct): ____ ____ • ____ ____ mg/dL

23. Aspartate aminotransferase (AST)

____ ____ ____ U/L

a. Upper limit of normal: ____ ____ U/L

24. Alanine aminotransferase (ALT)

____ ____ ____ U/L

a. Upper limit of normal: ____ ____ U/L

25. Alkaline phosphatase ____ ____ ____ U/L

a. Upper limit of normal: ____ ____ ____ U/L

26. Gamma glutamyl transferase (GGT):

____ ____ ____ U/L

27. Total protein: ____ ____ • ____ ____ g/dL

28. Albumin: ____ • ____ ____ g/dL

29. Prothrombin time (PT): ____ ____ • ____ ____ sec

30. International normalized ratio (INR):

____ • ____

E. Fasting lipid profile

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.

31. Was participant fasting for at least 8 hours prior to blood draw:

(Yes 1) (No * 2)

**12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

a. Triglycerides: ____ ____ ____ ____ mg/dL

b. Total cholesterol: ____ ____ ____ mg/dL

c. HDL cholesterol: ____ ____ ____ mg/dL

d. LDL cholesterol: ____ ____ ____ mg/dL

F. Fasting glucose and insulin

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.

33. Was participant fasting for at least 8 hours prior to blood draw:

(Yes 1) (No * 2)

35. ____

**Patient must be fasting; 12 hour fast is preferred.*

34. Date of blood draw for fasting glucose and insulin levels:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.

a. Serum glucose: ____ ____ ____
mg/dL

b. Serum insulin: ____ ____ ____ • ____ ____
µU/mL

G. Administrative information

35. Study Physician PIN: ____ ____ ____

36. Study Physician signature:

_____

37. Clinical Coordinator PIN: ____ ____ ____

38. Clinical Coordinator signature:

_____

39. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

LR - Laboratory Results - Tests Done During Screening and Follow-up

Purpose: To record archival and current laboratory test results for tests done during both screening and follow-up.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: Study Physician and Clinical Coordinator.

Instructions: All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit *(date form was initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t ____ ____ ____

6. Form & revision: 1 r 2

7. Study: NAFLD Database 2 6

B. Hematology

8. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. Mean corpuscular volume (MCV):

____ ____ ____
fL

12. White blood cell count (WBC):

____ ____ ____ • ____ ____
10^3 cells/µL or 10^9 cells/L

13. Platelet count:

____,____ ____ ____,____ ____ ____
cells/µL

C. Chemistries and HbA1c

14. Date of blood draw for chemistries:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

15. Blood urea nitrogen (BUN): ____ ____
mg/dL

16. Creatinine: ____ ____ • ____ ____
mg/dL

17. Uric acid: ____ ____ • ____ ____
mg/dL

18. Date of blood draw for HbA1c:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

19. HbA1c: ____ ____ • ____ ____
%

D. Liver panel

20. Date of blood draw for liver panel:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

21. Bilirubin (total): ____ ____ • ____ ____ mg/dL

22. Bilirubin (direct): ____ ____ • ____ ____ mg/dL

23. Aspartate aminotransferase (AST)

____ ____ ____ U/L

a. Upper limit of normal: ____ ____ U/L

24. Alanine aminotransferase (ALT)

____ ____ ____ U/L

a. Upper limit of normal: ____ ____ U/L

25. Alkaline phosphatase ____ ____ ____ ____ U/L

a. Upper limit of normal: ____ ____ ____ U/L

26. Gamma glutamyl transferase (GGT):

____ ____ ____ ____ U/L

27. Total protein: ____ ____ • ____ ____ g/dL

28. Albumin: ____ • ____ ____ g/dL

29. Prothrombin time (PT): ____ ____ • ____ ____ sec

30. International normalized ratio (INR):

____ • ____

E. Fasting lipid profile

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.

31. Was participant fasting for at least 8 hours prior to blood draw:

(Yes 1) (No * 2)

**12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

a. Triglycerides: ____ ____ ____ ____ mg/dL

b. Total cholesterol: ____ ____ ____ mg/dL

c. HDL cholesterol: ____ ____ ____ mg/dL

d. LDL cholesterol*: ____ ____ ____ mg/dL

**Enter "GT" if LDL cannot be calculated due to high triglycerides.*

F. Fasting glucose and insulin

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.

33. Was participant fasting for at least 8 hours prior to blood draw:

(Yes 1) (No * 2)

35. ____

**Patient must be fasting; 12 hour fast is preferred.*

34. Date of blood draw for fasting glucose and insulin levels:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.

a. Serum glucose: ____ ____ ____
mg/dL

b. Serum insulin: ____ ____ ____ • ____ ____
µU/mL

G. Administrative information

35. Study Physician PIN: ____ ____ ____

36. Study Physician signature:

_____

37. Clinical Coordinator PIN: ____ ____ ____

38. Clinical Coordinator signature:

_____

39. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

LR - Laboratory Results - Tests Done During Screening and Follow-up

Purpose: To record archival and current laboratory test results for tests done during both screening and follow-up.
When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.
Administered by: Study Physician and Clinical Coordinator.
Instructions: All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit *(date form was initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t ____ ____ ____

6. Form & revision: l r 3

7. Study: NAFLD Database 2 6

B. Hematology

8. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. Mean corpuscular volume (MCV):

____ ____ ____
fL

12. Blood cell count

a. White blood cell count (WBC):

____ ____ ____ • ____ ____
10^3 cells/μL or 10^9 cells/L

b. Red blood cell count (RBC):

____ ____ • ____ ____ ____
mill cells/μL

13. Platelet count:

____,____ ____ ____,____ ____ ____
cells/μL

C. Chemistries and HbA1c

14. Date of blood draw for chemistries:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

15. Blood urea nitrogen (BUN): ____ ____
mg/dL

16. Creatinine: ____ ____ • ____ ____
mg/dL

17. Uric acid: ____ ____ • ____ ____
mg/dL

18. Date of blood draw for HbA1c:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

19. HbA1c: ____ ____ • ____ ____
%

D. Liver panel

20. Date of blood draw for liver panel:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

21. Bilirubin (total): ____ ____ • ____ ____
mg/dL

22. Bilirubin (direct)*: ____ ____ • ____ ____
mg/dL

**If result is <0.2 or <0.1 , record 00.1 and indicate the actual result in a comment.*

23. Aspartate aminotransferase (AST)

____ ____ ____
U/L

a. Upper limit of normal: ____ ____
U/L

24. Alanine aminotransferase (ALT)

____ ____ ____
U/L

a. Upper limit of normal: ____ ____
U/L

25. Alkaline phosphatase ____ ____ ____ ____
U/L

a. Upper limit of normal: ____ ____ ____
U/L

26. Gamma glutamyl transferase (GGT):

____ ____ ____ ____
U/L

27. Total protein: ____ ____ • ____ ____
g/dL

28. Albumin: ____ • ____ ____
g/dL

29. Prothrombin time (PT): ____ ____ • ____ ____
sec

30. International normalized ratio (INR):

____ • ____ ____

E. Fasting lipid profile

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.

31. Was participant fasting for at least 8 hours prior to blood draw:

( ) Yes 1 ( ) No * 2

**12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).

a. Triglycerides: ____ ____ ____ ____
mg/dL

b. Total cholesterol: ____ ____ ____
mg/dL

c. HDL cholesterol: ____ ____ ____
mg/dL

d. LDL cholesterol*: ____ ____ ____
mg/dL

**Enter "GT" if LDL cannot be calculated due to high triglycerides.*

F. Fasting glucose and insulin

Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.

33. Was participant fasting for at least 8 hours prior to blood draw:

( ) Yes 1 ( ) No * 2

35. ____

**Patient must be fasting; 12 hour fast is preferred.*

34. Date of blood draw for fasting glucose and insulin levels:

____ ____–____ ____ ____–____ ____
day mon year

Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.

a. Serum glucose: ____ ____ ____
mg/dL

b. Serum insulin: ____ ____ ____ • ____ ____
μU/mL

G. Administrative information

35. Study Physician PIN: ____ ____ ____

36. Study Physician signature:

_____

37. Clinical Coordinator PIN: ____ ____ ____

38. Clinical Coordinator signature:

_____

39. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

LS - Laboratory Results - Tests Done only During Screening

Purpose: To record archival and current results of laboratory tests done only during screening.
When: Visit t0.
Administered by: Study Physician (adult hepatologist or pediatrician) and Clinical Coordinator.
Instructions:

New Database 2 patients: All laboratory test results are required at screening.

Continuing Database 2 patients: Laboratory tests may be repeated if clinically indicated.

Laboratory test results may be obtained from chart review. The acceptable time interval for archival laboratory data is specified for each test and recorded next to the date of blood draw. Laboratory tests should be repeated if the blood draw date is outside the specified time interval. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form. If EHG is checked for any item, you do not need to complete the rest of the form and the form should not be keyed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

6. Form & revision: 1 s 1

7. Study: NAFLD Database 2 6

8. Is the patient a continuing participant from Database, PIVENS, or TONIC:

(Yes 1) (No *2)

10.

**All laboratory test results are required during screening.*

9. Are new laboratory results available for the continuing participant:

(Yes *1) (No 2)

39.

**Record the date of blood draw as "m" if a test was not done.*

B. Screening etiologic tests

10. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

If the patient is judged by Study Physician to have a high-risk lifestyle, repeat if date is greater than 6 months prior to screening.

a. Hepatitis B surface antigen (HBsAg):
Positive (1) EHG
Negative (2)

b. Hepatitis B core total antibody (anti-HBc) *(if total anti-HBc is not available, record results from IgG test):*
Positive (1)
Negative (2)
Not available (3)

c. Hepatitis B surface antibody (anti-HBs):
Positive (1)
Negative (2)
Not available (3)

d. Hepatitis C antibody (anti-HCV) *(indicate result as negative if EIA is positive but RIBA is negative or if RIBA is indeterminate but HCV RNA is negative):*
Positive (1) EHG
Negative (2)

e. Hepatitis C virus RNA:

Positive (1) → Elig

Negative (2)

Not available (3)

f. Hepatitis A virus antibody *(anti-HAV, total):*

Positive (1)

Negative (2)

Not available (3)

C. Iron

11. Date of blood draw for iron overload screening:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

a. Iron: ____ ____ ____ µg/dL

b. Total iron binding capacity: ____ ____ ____ µg/dL

c. Ferritin: ____ ____ ____ ____ ng/mL

12. Is hepatic iron index available:

Yes (1) No (2)

→ **14.**

13. Hepatic iron index: ____ • ____ µMo1/g/year

D. HFE gene analysis

14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:

Yes (1) No (2)

→ **17.**

15. Date of blood draw for HFE gene analysis:

____ ____–____ ____ ____–____ ____
day mon year

16. Type of abnormality *(WT = wild type; check only one):*

None (0)

C282Y/H63D heterozygote mutation (1)

C282Y/C282Y homozygote mutation (2)

C282Y/WT heterozygote mutation (3)

H63D/WT heterozygote mutation (4)

H63D/H63D homozygote mutation (5)

E. Ceruloplasmin

17. Is patient 40 years old or younger:

Yes (1) No (2)

→ **20.**

18. Date of blood draw for ceruloplasmin: *(required only if patient is 40 years old or younger):*

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 10 years prior to screening.

19. Ceruloplasmin ____ ____ • ____ ____ mg/dL

a. Upper limit of normal: ____ ____ • ____ ____ mg/dL

b. Lower limit of normal: ____ ____ • ____ ____ mg/dL

F. Alpha-1 antitrypsin

20. Date of blood draw for alpha-1 antitrypsin (A1AT):

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 10 years prior to screening.

21. Alpha-1 antitrypsin (A1AT) ____ ____ ____ mg/dL

a. Upper limit of normal: ____ ____ ____ mg/dL

b. Lower limit of normal: ____ ____ ____ mg/dL

22. A1AT phenotype:

a. Pi Z heterozygote:

Yes (1)
No (2)
Unknown (3)

b. Pi ZZ homozygote:

Yes (1)
No (2)
Unknown (3)

23. A1AT deficiency *(physician judgment):*

Yes (1) → Elig
No (2)

G. Autoantibody studies

24. Date of blood draw for autoantibody tests:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

25. Antinuclear antibody (ANA):

Positive (*1)
Negative (2)
→ **26.**

**If positive ANA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

26. Antismooth muscle antibody (ASMA):

Positive (*1)
Negative (2)
→ **27.**

**If positive ASMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

27. Antimitochondrial antibody (AMA):

Positive (*1)
Negative (2)
→ **28.**
Age < 18 and not done (3)
→ **28.**

**If positive AMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

28. Is patient 18 or older:

Yes (1) → **32.**
No (2)

29. Lymphocytotoxic antibody (LCA):

Positive (*1)
Negative (2)
→ **30.**
Not available (3)
→ **30.**

**If positive LCA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

30. Antibody to liver-kidney microsomal antigen (LKM1):

Positive (*1)
Negative (2)
31.
Not available (3)
31.

**If positive LKM1 value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

31. Rheumatoid factor (RF):

Positive (*1)
Negative (2)
32.
Not available (3)
32.

**If positive, record RF value.*

a. Units: ____ ____ • ____
IU/mL

If results are given as a titer, record as ''n'' and key the actual result in the General Comments.

H. Immunoglobulin levels

32. Are immunoglobulin levels available:

Yes (1) No (2)
37.

33. Date of blood draw for immunoglobulin levels:

____ ____–____ ____ ____–____ ____
day mon year

34. IgA: ____ ____ ____
mg/dL

35. IgG:

____ ____ ____ ____
mg/dL

36. IgM: ____ ____ ____
mg/dL

I. Other screening blood tests

37. Date of blood draw for thyroid stimulating hormone (TSH)*:

____ ____–____ ____ ____–____ ____
day mon year

*Repeat if date is greater than 5 years prior to screening. *Optional if patient under age 18; enter ''m'' if not done.*

38. Thyroid stimulating hormone:

____ ____ • ____ ____
μU/mL

J. Administrative information

39. Study Physician PIN: ____ ____ ____

40. Study Physician signature:

_____

41. Clinical Coordinator PIN: ____ ____ ____

42. Clinical Coordinator signature:

_____

43. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

LS - Laboratory Results - Tests Done only During Screening

Purpose: To record archival and current results of laboratory tests done only during screening.
When: Visit t0.
Administered by: Study Physician (adult hepatologist or pediatrician) and Clinical Coordinator.
Instructions:

New Database 2 patients: All laboratory test results are required at screening.

Continuing Database 2 patients: Laboratory tests may be repeated if clinically indicated.

Laboratory test results may be obtained from chart review. The acceptable time interval for archival laboratory data is specified for each test and recorded next to the date of blood draw. Laboratory tests should be repeated if the blood draw date is outside the specified time interval. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form. If EHG is checked for any item, you do not need to complete the rest of the form and the form should not be keyed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

6. Form & revision: l s 2

7. Study: NAFLD Database 2 6

8. Is the patient a continuing participant from Database, PIVENS, or TONIC:

Yes (1) No (*2)

10.

**All laboratory test results are required during screening.*

9. Are new laboratory results available for the continuing participant:

Yes (*1) No (2)

39.

**Record the date of blood draw as "m" if a test was not done.*

B. Screening etiologic tests

10. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

If the patient is judged by Study Physician to have a high-risk lifestyle, repeat if date is greater than 6 months prior to screening.

a. Hepatitis B surface antigen (HBsAg):
Positive (1) EHG ____
Negative (2)

b. Hepatitis B core total antibody (anti-HBc) *(if total anti-HBc is not available, record results from IgG test):*
Positive (1)
Negative (2)
Not available (3)

c. Hepatitis B surface antibody (anti-HBs):
Positive (1)
Negative (2)
Not available (3)

d. Hepatitis C antibody (anti-HCV) *(indicate result as negative if EIA is positive but RIBA is negative or if RIBA is indeterminate or unavailable but HCV RNA is negative):*
Positive (1) EHG ____
Negative (2)

e. Hepatitis C virus RNA:

Positive (1)

Negative (2)

Not available (3)

f. Hepatitis A virus antibody *(anti-HAV, total):*

Positive (1)

Negative (2)

Not available (3)

C. Iron

11. Date of blood draw for iron overload screening:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

a. Iron: ____ ____ ____ µg/dL

b. Total iron binding capacity: ____ ____ ____ µg/dL

c. Ferritin: ____ ____ ____ ____ ng/mL

12. Is hepatic iron index available:

Yes (1) No (2)

14.

13. Hepatic iron index: ____ • ____ µMo1/g/year

D. HFE gene analysis

14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:

Yes (1) No (2)

17.

15. Date of blood draw for HFE gene analysis:

____ ____–____ ____ ____–____ ____
day mon year

16. Type of abnormality *(WT = wild type; check only one):*

None (0)

C282Y/H63D heterozygote mutation (1)

C282Y/C282Y homozygote mutation (2)

C282Y/WT heterozygote mutation (3)

H63D/WT heterozygote mutation (4)

H63D/H63D homozygote mutation (5)

E. Ceruloplasmin

17. Is patient 40 years old or younger:

Yes (1) No (2)

18.

a. Is a ceruloplasmin value available:

Yes (1) No (2)

20.

18. Date of blood draw for ceruloplasmin: *(required only if patient is 40 years old or younger; record if available if patient is greater than 40 years old):*

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 10 years prior to screening.

19. Ceruloplasmin ____ ____ • ____ mg/dL

a. Upper limit of normal: ____ ____ • ____ mg/dL

b. Lower limit of normal: ____ ____ • ____ mg/dL

F. Alpha-1 antitrypsin

20. Date of blood draw for alpha-1 antitrypsin (A1AT):

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 10 years prior to screening.

21. Alpha-1 antitrypsin (A1AT) ___ ___ ___ mg/dL

a. Upper limit of normal: ___ ___ ___ mg/dL

b. Lower limit of normal: ___ ___ ___ mg/dL

22. A1AT phenotype:

a. Pi Z heterozygote:

Yes (1)
No (2)
Unknown (3)

b. Pi ZZ homozygote:

Yes (1)
No (2)
Unknown (3)

23. A1AT deficiency *(physician judgment):*

Yes (1) No (2)
Elig

G. Autoantibody studies

24. Date of blood draw for autoantibody tests:

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 5 years prior to screening.

25. Antinuclear antibody (ANA):

Positive (*1)
Negative (2)
26.

**If positive ANA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/___ ___ ___ ___

b. Units: ___ ___ • ___

26. Antismooth muscle antibody (ASMA):

Positive (*1)
Negative (2)
27.

**If positive ASMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/___ ___ ___ ___

b. Units: ___ ___ • ___

27. Antimitochondrial antibody (AMA):

Positive (*1)
Negative (2)
28.
Age < 18 and not done (3)
28.

**If positive AMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/___ ___ ___ ___

b. Units: ___ ___ • ___

28. Is patient 18 or older:

Yes (1) No (2)
32.

29. Lymphocytotoxic antibody (LCA):

Positive (*1)
Negative (2)
30.
Not available (3)
30.

**If positive LCA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/___ ___ ___ ___

b. Units: ___ ___ • ___

30. Antibody to liver-kidney microsomal antigen (LKM1):

Positive (*1)
Negative (2)
31. ___
Not available (3)
31. ___

**If positive LKM1 value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ___ ___ ___ ___

b. Units: ___ ___ • ___

31. Rheumatoid factor (RF):

Positive (*1)
Negative (2)
32. ___
Not available (3)
32. ___

**If positive, record RF value.*

a. Units: ___ ___ • ___
IU/mL

If results are given as a titer, record as "n" and key the actual result in the General Comments.

H. Immunoglobulin levels

32. Are immunoglobulin levels available:

Yes (1) No (2)
37. ___

33. Date of blood draw for immunoglobulin levels:

___ ___–___ ___ ___–___ ___
day mon year

34. IgA: ___ ___ ___
mg/dL

35. IgG: ___ ___ ___ ___
mg/dL

36. IgM: ___ ___ ___
mg/dL

I. Other screening blood tests

37. Date of blood draw for thyroid stimulating hormone (TSH)*:

___ ___–___ ___ ___–___ ___
day mon year

*Repeat if date is greater than 5 years prior to screening. *Optional if patient under age 18; enter "m" if not done.*

38. Thyroid stimulating hormone:

___ ___ • ___ ___
μU/mL

J. Administrative information

39. Study Physician PIN: ___ ___ ___

40. Study Physician signature:

_____

41. Clinical Coordinator PIN: ___ ___ ___

42. Clinical Coordinator signature:

_____

43. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

NAFLD Database 2

LS - Laboratory Results - Tests Done only During Screening

Purpose: To record archival and current results of laboratory tests done only during screening.
When: Visit t0.
Administered by: Study Physician (adult hepatologist or pediatrician) and Clinical Coordinator.
Instructions:

New Database 2 patients: All laboratory test results are required at screening.

Continuing Database 2 patients: Laboratory tests may be repeated if clinically indicated.

Laboratory test results may be obtained from chart review. The acceptable time interval for archival laboratory data is specified for each test and recorded next to the date of blood draw. Laboratory tests should be repeated if the blood draw date is outside the specified time interval. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form. If EHg is checked for any item, you do not need to complete the rest of the form and the form should not be keyed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

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8. Is the patient a continuing participant from Database, PIVENS, or TONIC:

Yes (1) No (*2)

10.

**All laboratory test results are required during screening.*

9. Are new laboratory results available for the continuing participant:

Yes (*1) No (2)

39.

**Record the date of blood draw as "m" if a test was not done.*

B. Screening etiologic tests

10. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:

____ ____–____ ____ ____–____ ____
day mon year

Repeat if date is greater than 5 years prior to screening.

If the patient is judged by Study Physician to have a high-risk lifestyle, repeat if date is greater than 6 months prior to screening.

a. Hepatitis B surface antigen (HBsAg):
Positive (1) EHg ____
Negative (2)

b. Hepatitis B core total antibody (anti-HBc) *(if total anti-HBc is not available, record results from IgG test):*
Positive (1)
Negative (2)
Not available (3)

c. Hepatitis B surface antibody (anti-HBs):
Positive (1)
Negative (2)
Not available (3)

d. Hepatitis C antibody (anti-HCV) *(indicate result as negative if EIA is positive but RIBA is negative or if RIBA is indeterminate or unavailable but HCV RNA is negative):*
Positive (1) EHg ____
Negative (2)

e. Hepatitis C virus RNA:

Positive (1) 

Negative (2)

Not available (3)

f. Hepatitis A virus antibody *(anti-HAV, total):*

Positive (1)

Negative (2)

Not available (3)

C. Iron

11. Date of blood draw for iron overload screening:

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 5 years prior to screening.

a. Iron: ___ ___ ___ µg/dL

b. Total iron binding capacity: ___ ___ ___ µg/dL

c. Ferritin: ___ ___ ___ ___ ng/mL

12. Is hepatic iron index available:

Yes (1) No (2)

14.

13. Hepatic iron index: ___ • ___ µMo1/g/year

D. HFE gene analysis

14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:

Yes (1) No (2)

17.

15. Date of blood draw for HFE gene analysis:

___ ___–___ ___ ___–___ ___
day mon year

16. Type of abnormality *(WT = wild type; check only one):*

None (0)

C282Y/H63D heterozygote mutation (1)

C282Y/C282Y homozygote mutation (2)

C282Y/WT heterozygote mutation (3)

H63D/WT heterozygote mutation (4)

H63D/H63D homozygote mutation (5)

E. Ceruloplasmin

17. Is patient 40 years old or younger:

Yes (1) No (2)

18.

a. Is a ceruloplasmin value available:

Yes (1) No (2)

20.

18. Date of blood draw for ceruloplasmin: *(required only if patient is 40 years old or younger; record if available if patient is greater than 40 years old):*

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 10 years prior to screening.

19. Ceruloplasmin ___ ___ • ___ mg/dL

a. Upper limit of normal: ___ ___ • ___ mg/dL

b. Lower limit of normal: ___ ___ • ___ mg/dL

F. Alpha-1 antitrypsin

20. Date of blood draw for alpha-1 antitrypsin (A1AT):

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 10 years prior to screening.

21. Alpha-1 antitrypsin (A1AT) ___ ___ ___ mg/dL

a. Upper limit of normal: ___ ___ ___ mg/dL

b. Lower limit of normal: ___ ___ ___ mg/dL

22. A1AT phenotype* *(check only one):*

MM	(1)
MS	(2)
MZ	(3)
SZ	(4)
ZZ	(5)
Other *(specify):*	(6)

_____
specify

Not available	(7)

**If the phenotype result includes numbers, the numbers should be disregarded when reporting the result (e.g., M1M2 should be reported as MM).*

23. Is A1AT deficiency the primary cause of this patient's liver disease *(physician assessment):*

Yes (1) No (2)

EHg

G. Autoantibody studies

24. Date of blood draw for autoantibody tests:

___ ___–___ ___ ___–___ ___
day mon year

Repeat if date is greater than 5 years prior to screening.

25. Antinuclear antibody (ANA):

Positive	(*1)
Negative	(2)

26.

**If positive ANA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ___ ___ ___ ___

b. Units: ___ ___ • ___

26. Antismooth muscle antibody (ASMA):

Positive	(*1)
Negative	(2)

27.

**If positive ASMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ___ ___ ___ ___

b. Units: ___ ___ • ___

27. Antimitochondrial antibody (AMA):

Positive	(*1)
Negative	(2)

28.

Age < 18 and not done	(3)

28.

**If positive AMA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ___ ___ ___ ___

b. Units: ___ ___ • ___

28. Is patient 18 or older:

Yes (1) No (2)

32.

29. Lymphocytotoxic antibody (LCA):

Positive (*1)
Negative (2)
30. ___
Not available (3)
30. ___

**If positive LCA value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

30. Antibody to liver-kidney microsomal antigen (LKM1):

Positive (*1)
Negative (2)
31. ___
Not available (3)
31. ___

**If positive LKM1 value, complete either a or b depending on laboratory results:*

a. Titer *(record only the denominator):*

1/ ____ ____ ____ ____

b. Units: ____ ____ • ____

31. Rheumatoid factor (RF):

Positive (*1)
Negative (2)
32. ___
Not available (3)
32. ___

**If positive, record RF value.*

a. Units: ____ ____ • ____
IU/mL

If results are given as a titer, record as "n" and key the actual result in the General Comments.

H. Immunoglobulin levels

32. Are immunoglobulin levels available:

Yes (1) No (2)
37. ___

33. Date of blood draw for immunoglobulin levels:

____ ____–____ ____ ____–____ ____
day mon year

34. IgA: ____ ____ ____ mg/dL

35. IgG: ____ ____ ____ ____ mg/dL

36. IgM: ____ ____ ____ mg/dL

I. Other screening blood tests

37. Date of blood draw for thyroid stimulating hormone (TSH)*:

____ ____–____ ____ ____–____ ____
day mon year

*Repeat if date is greater than 5 years prior to screening. *Optional if patient under age 18; enter "m" if not done.*

38. Thyroid stimulating hormone:

____ ____ • ____ ____
μU/mL

J. Administrative information

39. Study Physician PIN: ____ ____ ____

40. Study Physician signature:

_____

41. Clinical Coordinator PIN: ____ ____ ____

42. Clinical Coordinator signature:

_____

43. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

NAFLD Database 2

PE - Physical Examination

Purpose: Record physical exam findings of NAFLD Database 2 patients.

When: Visits t0, t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Details of the protocol for height, weight, waist and hip measurement are found in the NAFLD Database 2 SOP I. In brief: height, weight, waist and hips should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Repeat waist measurements until you have two measurements within 4 inches (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 inches (10.2 cm) of each other.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t ____ ____ ____

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B. Measurements

8. Height *(shoes off - repeat height measurements until you have two measurements within 0.5 inches (1.3 cm) of each other):*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)
Centimeters (2)

9. Weight *(shoes off - repeat weight measurements until you have two measurements within 2 lbs (0.91 kg) of each other):*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Pounds (1)
Kilograms (2)

10. Waist *(standing, at midpoint between highest point of iliac crest and lowest point of costal margin; repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)
Centimeters (2)

11. Hip *(standing, at fullest part of the hips; repeat hip measurements until you have two measurements within 4 inches (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)
Centimeters (2)

12. Temperature *(oral or other as appropriate for age):*

a. Degrees: ___ ___ ___ • ___

b. Scale:

Fahrenheit: (1)

Centigrade: (2)

13. Blood pressure

a. Systolic: ___ ___ ___ mmHg

b. Diastolic: ___ ___ ___ mmHg

14. Resting radial pulse: ___ ___ ___ beats/minute

15. Respiratory rate: ___ ___ breaths/minute

C. Examination findings

16. Areas with acanthosis nigricans *(check all that apply):*

a. None: (1)

b. Neck: (1)

c. Axilla: (1)

d. Elbows: (1)

e. Knees: (1)

f. Knuckles: (1)

g. Periumbilical: (1)

17. Abdomen abnormalities present *(check all that apply):*

a. None: (1)

b. Ascites: (1)

c. Obese: (1)

d. Splenomegaly: (1)

e. Hepatomegaly: (1)

If Yes, span at right midclavicular line:

___ ___ • ___ cm

D. Liver signs

18. Focused liver signs *(check all that apply)*

a. None: (1)

b. Jaundice: (1)

c. Palmar erythema: (1)

d. Contractures: (1)

e. Pedal edema: (1)

f. Spider angiomata: (1)

g. Asterixis: (1)

h. Hepatic encephalopathy: (1)

i. Other, *(specify):* (1)

_____ specify

E. Tanner Staging

19. Is Tanner staging required for this patient *(Note: Required during screening if patient is 17 years old or younger.) (check only one):*

Yes, patient has not reached full sexual maturity and is 17 years old or younger: (1)

No, patient is 18 years old or older (2)

27. ___

No, participant had reached full sexual maturity *(Tanner stage 5 on all parameters at screening or for 2 consecutive visits)* (3)

27. ___

20. Is the patient female:

Yes (1) No (2)

23. ___

Male Tanner Staging

21. Genital stage: ___ 1-5

22. Pubic hair stage: ___ 1-5

27. ___

Female Tanner Staging

23. Breast stage: ____ (1-5)

24. Pubic hair stage: ____ (1-5)

25. Has menarche occurred:

( ) Yes (1) ( ) No (2)

27.

26. If yes, what was the patient's age at menarche:

____ ____ age in years

F. Administrative information

27. Study Physician PIN: ____ ____ ____

28. Study Physician signature:

_____

29. Clinical Coordinator PIN: ____ ____ ____

30. Clinical Coordinator signature:

_____

31. Date form reviewed:

____ ____–____ ____ ____–____ ____

day mon year

NAFLD Database 2

RG - Registration

Purpose: To register patients as candidates for enrollment in the NAFLD Database 2 study and to assign a patient ID number. This is the first form completed for a NAFLD Database 2 patient. The Registration Form must be the first form keyed, before any other NAFLD Database 2 forms.

When: At first screening visit (t0).

Administered by: Clinical Coordinator.

Respondent: Patient and parent (if patient is age 17 or younger).

Instructions: Use Flash Cards as instructed. Do not assign an ID if patient has previously been assigned an ID for a NASH CRN study.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: t 0 ____ ____

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B. Consent

8. Has the patient (or patient's guardian) signed the NAFLD Database 2 informed consent statement:

Yes (1) No (2)

STOP

C. Information about patient

9. Date of birth:

____ ____–____ ____ ____–____ ____ ____ ____
day month year

Record 4-digit year for date of birth.

10. Age at last birthday: ____ ____
years

11. Gender:

Male (1)
Female (2)

12. Ethnic category *(show the patient/parent Flash Card #1 and ask the respondent to pick the category that describes the patient best; check only one):*

Hispanic or Latino or Latina (1)
Not Hispanic, not Latino, not Latina (2)

14.

13. What describes your Hispanic, Latino, or Latina origin best *(show the patient/parent Flash Card #1 and ask the respondent to pick the subcategory that best describes their Hispanic, Latino, or Latina origin; check only one):*

Mexican (1)
Puerto Rican (2)
Cuban (3)
South or Central American (4)
Other Spanish culture or origin (5)

_____
specify

14. Racial category *(show the patient/parent Flash Card #2 and ask the respondent to pick the category or categories that describe the patient best; check all that apply)*

a. American Indian or Alaska Native: (1)
b. Asian: (1)
c. Black, African American, Negro, or Haitian: (1)
d. Native Hawaiian or other Pacific Islander: (1)
e. White: (1)
f. Patient refused: (1)

15. In what country was the patient born *(check only one):*

Continental US (includes Alaska) or Hawaii (1)
Other, *(specify):* (2)

_____
specify

16. Highest educational level achieved by patient *(show the patient/parent Flash Card #3 and ask the respondent to pick the category that describes the patient best; check only one):*

Never attended school	(0)
Kindergarten, pre kindergarten, or younger	(1)
Grades 1 to 5	(2)
Grades 6-8	(3)
Grades 9-11	(4)
Completed high school	(5)
Some college or post high school education or training	(6)
Bachelor's degree or higher	(7)

17. Is the patient currently employed:

(Yes 1) (No 2)

20. ___

18. What is the patient's current occupation:

_____
specify occupation

19. About how many hours does the patient work each week: ___ ___
hours

20. Which of the following categories best characterizes the patient's occupational history *(show the patient/parent Flash Card #4 and ask the respondent to pick the category that describes the patient best; check only one):*

Never employed	(0)
Laborer	(1)
Clerical	(2)
Professional	(3)
Homemaker	(4)
Other, *(specify):*	(5)

_____
specify

21. Marital status of the patient *(show the patient/parent Flash Card #5 and ask the respondent to pick the category that describes the patient best; check only one):*

Single, never married	(1)
Married or living in marriage-like relationship	(2)
Separated, divorced, or annulled	(3)
Widowed	(4)

22. Combined annual income before taxes of all members of patient's household *(show the patient/parent Flash Card #6 and ask the respondent to pick the category that describes the patient's combined household income best; check only one):*

Less than $15,000	(1)
$15,000 - $29,999	(2)
$30,000 - $49,999	(3)
$50,000 or more	(4)

D. Previous registration in a NASH CRN study

23. Has the patient ever been assigned an ID number in a NASH CRN study:

(Yes 1) (No 2)

27. ___

24. In which NASH CRN studies has the patient previously been registered *(check all that apply)*

a. Database:	(1)
b. PIVENS:	(1)
c. TONIC:	(1)
d. Other, *(specify):*	(1)

_____
specify

25. ID Number previously assigned to patient *(record patient ID in item 2):*

___ ___ ___ ___

26. Code previously assigned to patient *(record patient code in item 3):*

___ ___ ___

28. ___

F. ID assignment

(If a STOP condition was checked in section B, the patient is ineligible and a Patient ID should not be assigned. If the patient was previously registered in a NASH CRN study, a new ID number should not be assigned.)

27. Place ID label below and record Patient ID in item 2 and patient code in item 3.

CCCC ####, zzz

G. Administrative information

28. Clinical Coordinator PIN: ____ ____ ____

29. Clinical Coordinator signature:

_____

30. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year