Keyed: ( )

NAFLD Database

AD – Alcohol Use Disorders Identification Test (AUDIT)

Purpose: To screen for current heavy drinking and/or active alcohol abuse or dependence.
When: Visit s1.
Administered by: Self-administered *(age 13 or older)*, interviewer administered *(age 8-12)*. Clinical Coordinator must be available at visits to answer questions and review completed forms.
Respondent: Patient, age 8 or older. Patients age 13 or older should complete the form without help from spouse or family. Clinical Coordinator/parent can assist patients age 8-12.
Instructions: Flash Card #15, 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. If the form is self-administered by the patient, 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: **s 1** _____ _____

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

7. Study: NAFLD Database 1

B. Administrative information

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

8. How was the questionnaire completed:

Self-administered by patient (1)
→ **10.**

Interview in English (2)
Interview with translator (3)

9. Who was the respondent *(check all that apply)*:

a. Patient: (1)
b. Patient's mother or female guardian: (1)
c. Patient's father or male guardian: (1)
d. Other *(specify)*: (1)

_____
specify

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

_____

11. 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 1-11 are for clinical center use only)* .

12. 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)	(1)	(2)	(3)	(4)

→ **22.**

13. 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)

14. 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)

15. 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)

16. 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)

17. 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)

18. 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)

19. 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)

20. 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)

21. 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)

22. Today's date:

_____

Thank you for completing this questionnaire.

NAFLD Database

BG - Baseline History

Purpose: To collect baseline history information about the patient.
When: Visit s1.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient or patient's parent.
Instructions: Collect information by interview or chart review. If C is checked for an item, use caution. If the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database. If EXC is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database. The form should not be keyed to the data system, but the form should be retained; 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: s 1 ____ ____

6. Form & revision: b g 3

7. Study: NAFLD Database 1

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. Primary liver cancer: (1)
i. Type of liver disease unknown: (1)
j. 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 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 cryptogenic cirrhosis:

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

17. What prompted the evaluation for NAFLD, NASH, or cryptogenic 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 procedure/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 one or more liver biopsies done prior to registration in the Database that you want evaluated for the Database:

Yes (1) No (2)

21. ___

20. Liver biopsy(s) prior to registration in the Database that you want evaluated

a. Date of most recent liver biopsy that you want evaluated for the Database *(complete form SE [Most Recent Prior Liver Biopsy Materials Documentation] for this biopsy):*

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

b. Does the patient have another biopsy, older than the biopsy noted in item 20a, that you want evaluated for the Database:

Yes (1) No (2)
21.

c. Date of next most recent liver biopsy that you want evaluated for the Database *(complete form SF [Next Most Recent Prior Liver Biopsy Materials Documentation] for this biopsy):*

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

21. Will the patient have a biopsy during screening:

Yes (* 1) No (2)

**Complete the Liver Biopsy Materials Documentation (SD) form for this biopsy.*

22. Has the patient had a liver imaging study (ultrasound, MRI, or CT scan) in the past year:

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 17.* 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 8 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):*

C 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 you didn't stop smoking):*

____ ____
years

42. On the average of the entire time 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. 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

(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. Iron overload: (1) C

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) C

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

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

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

z. Hepatocellular carcinoma: (1) C

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) C

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)

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: (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) → Flg

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) in the past 2 years:

(Yes 1) (No 2)

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

(Yes 1) (No 2)

H. Medication use

54. Has the patient used any antidiabetic medications in the past 6 months *(check all that apply):*

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)

_____

q. None of the above: (1)

55. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 6 months *(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)

_____

h. None of the above: (1)

56. Has the patient taken any antihyperlipidemic medications in the past 6 months *(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)

_____

m. None of the above: (1)

57. Has the patient taken any antiobesity medications in the past 6 months *(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)

_____

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

_____

j. None of the above: (1)

58. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 6 months *(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)

_____

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

_____

l. None of the above: (1)

59. Has the patient taken any strong opiates containing acetaminophen medication in the past 6 months *(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)

_____

o. None of the above: (1)

60. Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications in the past 6 months *(check all hat 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)

_____

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

_____

l. None of the above: (1)

61. Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months *(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)

_____

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

_____

h. None of the above: (1)

62. Has the patient taken any systemic corticosteroids in the past 6 months *(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)

_____

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

_____

l. None of the above: (1)

63. Has the patient taken any cardiovascular or antihypertensive medications in the past 6 months *(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)

_____

ac. None of the above: (1)

64. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months *(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 (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (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)

_____

v. None of the above: (1)

65. Has the patient taken any allergy or asthma medications in the past 6 months *(check all that apply):*

a. Albuterol: (1)

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

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

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

e. Loratadine (Claritin): (1)

f. Mometasone furoate (Nasonex): (1)

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

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

_____

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

_____

j. None of the above: (1)

66. Has the patient taken a multivitamin regularly in the past 6 months:

Yes (1) No (2)

67. Has the patient taken vitamins other than multivitamins in the past 6 months:

Yes (1) No (2)

69.

68. 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)

_____

69. Has the patient taken any supplements in the past 6 months *(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)

_____

ae. None of the above: (1)

70. Has patient taken any of the following medications or other supplements/medications in the past 6 months *(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)

_____

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

_____

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

_____

u. None of the above: (1)

I. Administrative information

71. Study Physician PIN: ____ ____ ____

72. Study Physician signature:

_____

73. Clinical Coordinator PIN: ____ ____ ____

74. Clinical Coordinator signature:

_____

75. 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 1 6. Form and revision

__ 7. Study: **1**=Database; **2**=PIVENS; **3**=TONIC

__ __ / __ __ __ / __ __ 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

__ __ . . . d. Other slide

_____ . . . . . Specify type of stain for other slide

C. Administrative information

__ __ __ 10. CC Initials

_____ 11. CC Signature

__ __ / __ __ __ / __ __ 12. Date form reviewed

__ 13. Tissue adequate: **0**=No ➜ Request original slides from submitting clinic; **1**=Yes

_____ 14. Followup with clinic (*Specify*):

_____ *Patient ID* **D. Histology**

_____ 15. Biopsy length (mm)

H & E stain

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

17. 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. Microgranulomas 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

18. Liver cell injury

_____ . . . a. Ballooning: **0**=None; **1**=Few; **2**=Many

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

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

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

_____ 19. Mallory's hyaline: **0**=Rare/absent; **1**=Many

_____ 20. Glycogen nuclei: **0**=Rare/absent; **1**=Many

Masson's trichrome stain

_____ 21. Fibrosis stage: **0**=None; **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

22. Iron stain

_____ . . . a. Hepatocellular iron grade: **0**=Absent or barely discernible, 40x ➜ **GOTO item 22c**;
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 23**; **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

_____ 23. Is this steatohepatitis? **0**=No; **1a**=Suspicious/borderline/indeterminate: Zone 3 pattern;
1b=Suspicious/borderline/indeterminate: Zone 1, periportal pattern; **2**=Yes, definite

_____ 24. Is cirrhosis present? **0**=No ➜ **GOTO item 27**; **1**=Yes

_____ 25. Is this cryptogenic cirrhosis: **0**=No ➜ **GOTO item 27**; **1**=Yes

26. Features suggestive of steatohepatitis etiology for cryptogenic cirrhosis:

_____ . . . a. Mallory's hyaline (*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: _____

27. Other comments: _____

NAFLD Database

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 this form whenever the clinical center is informed of a patient's death. If the death is considered associated or possibly associated with participation in the NAFLD Database, complete a Serious Adverse Event (AN) form and follow the directions on Form AN for reporting a SAE in the NAFLD Database.

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 1

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

F. Eligibility check

23. Was an ineligibility condition checked or an eligibility not ascertained in items 8-14 or item 22:

Yes (1) No (2)

26.

Instructions: Key visits s1 and s2 forms: RG and AD, BC, BD, BG, BP, CG, HF, IR, LD, LP/LQ, LR, LS, PA/MA, PE, PF, QF/PQ, PR, PS, PT, PV, PW, PY as appropriate. Run the Enrollment Task on your clinic data system.

24. Were any STOP's or ineligible conditions other than ''missing Form ED'' identified by the Enrollment Task:

Yes (1)

26.

No (2)

Task not run because patient is known to be ineligible (* 3)

26.

**You can skip running the Enrollment Task if you already know that the patient is ineligible; you must run the task to enroll the patient.*

25. Does the patient/parent still consent/assent to enrollment *(you should ask the patient/parent to orally affirm his/her consent/assent):*

Yes (* 1) No (2)

27. Elig

**Go to item 27 and complete this form. Then key this form and run the Enrollment Task on your clinic data system to enroll the patient.*

G. Reasons for ineligibility for ineligible patients

NOTE: Complete this section for ineligible patients only.

26. Reason for ineligibility *(check all that apply)*

a. Reason covered in items 8-14, 22, or 25: (1)

b. Tests are outside time window and clinic chose not to repeat tests: (1)

c. Other reason not covered on this form *(specify):* (1)

_____

H. 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

HI - Followup Medical History

Purpose: To record followup medical history information about the patient.
When: f024, f048, f096, f144, and f192.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient.
Instructions: Collect information by interview or 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: ____ ____ ____ ____

6. Form & revision: h i 1

7. Study: NAFLD Database 1

B. Interval identification

8. Date of last Followup Medical History form *(if this is visit f024 then date of s1):*

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

9. Visit code of last Followup Medical History form *(if this is visit f024 then s1):*

____ ____ ____ ____

C. NAFLD evaluation

10. Has the patient had a liver biopsy since the last visit:

Yes (*1) No (2)

**Complete the Liver Biopsy Materials Documentation (SD) form.*

11. Has the patient 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 8 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 *(check all that apply):*

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)

_____

q. None of the above: (1)

27. Since the last visit, has the patient taken any alcohol abuse (dependance or withdrawal) medications *(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)

_____

h. None of the above: (1)

28. Since the last visit, has the patient taken any antihyperlipidemic medications *(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)

_____

m. None of the above: (1)

29. Since the last visit, has the patient taken any antiobesity medications *(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)

_____

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

_____

j. None of the above: (1)

30. Since the last visit, has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications *(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. Other, *(specify):* (1)

_____

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

_____

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

_____

k. None of the above: (1)

31. Has the patient taken any strong opiates containing acetaminophen medication in the past 6 months *(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)

_____

o. None of the above: (1)

32. Since the last visit, has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications *(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)

_____

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

_____

l. None of the above: (1)

33. Since the last visit, has the patient taken any anticoagulant/antiplatelet medications *(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)

_____

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

_____

h. None of the above: (1)

34. Since the last visit, has the patient taken any systemic corticosteroids *(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)

_____

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

_____

l. None of the above: (1)

35. Since the last visit, has the patient taken any cardiovascular/antihypertensive medications *(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)

_____

ac. None of the above: (1)

36. Since the last visit, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators *(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 (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (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)

_____

v. None of the above: (1)

37. Since the last visit, has the patient taken any allergy or asthma medications *(check all that apply):*

a. Albuterol: (1)

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

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

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

e. Loratadine (Claritin): (1)

f. Mometasone furoate (Nasonex): (1)

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

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

_____

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

_____

j. None of the above: (1)

38. Since the last visit, has the patient taken a multivitamin regularly:

Yes (1) No (2)

39. Since the last visit, has the patient taken vitamins other than multivitamins:

Yes (1) No (2)

41.

40. 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)

_____

41. Since the last visit, has the patient taken any supplements *(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)

_____

ae. None of the above: (1)

42. Since the last visit, has patient taken any of the following medications or other supplements/medications *(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)

_____

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

_____

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

_____

u. None of the above: (1)

H. Summary judgments about specific liver conditions *(these judgments are to be made after all of the visit data are collected)*

43. 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

44. Study Physician PIN: ____ ____ ____

45. Study Physician signature:

_____

46. Clinical Coordinator PIN: ____ ____ ____

47. Clinical Coordinator signature:

_____

48. Date form reviewed:

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

NAFLD Database

IE - Interim Event Report

Purpose: To document (1) events that occur after registration but before enrollment, or between regular followup visits, that impact on the patient's participation in NAFLD Database (eg, mild or moderate liver biopsy complications), or (2) adverse events associated with study participation that do not meet the criteria for Serious Adverse Event Report (AN), or (3) other event that clinical center staff feel should be reported now rather than wait until the next followup visit and that is not recorded on another NAFLD Database 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 21) and the severity code (item 22) 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: Aynur Ünalp-Arida) 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 1

B. Visit interval identification

8. Most recently completed visit (screening or followup)

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

b. Visit code: ____ ____ ____ ____

C. Patient information

9. Date enrolled in NAFLD Database *(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. Is the event associated with prior PIVENS study drug use:

Yes (1) No (2)

16.

14. Is the event due to the pioglitazone-series study drug:

Definitely yes (1)
Probably yes (2)
Possibly yes (3)
Probably no (4)
Definitely no (5)

15. Is the event due to the vitamin E-series study drug:

Definitely yes	(1)
Probably yes	(2)
Possibly yes	(3)
Probably no	(4)
Definitely no	(5)

16. Is the event associated with prior TONIC study drug use:

(Yes 1) (No 2)

19.

17. Is the event due to the metformin-series study drug:

Definitely yes	(1)
Probably yes	(2)
Possibly yes	(3)
Probably no	(4)
Definitely no	(5)

18. Is the event due to the vitamin E-series study drug:

Definitely yes	(1)
Probably yes	(2)
Possibly yes	(3)
Probably no	(4)
Definitely no	(5)

19. Nature of event *(check all that apply)*

a. General anesthesia:	(1)
b. Medication related event:	(1)
c. Study procedure related event:	(1)
d. Drug interactions:	(1)
e. Worsening of a co-morbid illness:	(1)
f. Patient reported symptom of hepatotoxicity:	(1)
g. Hypoglycemia:	(1)
h. New-onset diabetes:	(1)
i. Pregnancy *(patient):*	(1)
j. Other *(specify):*	(1)

_____

_____

20. Describe event:

_____

_____

_____

_____

_____

_____

21. 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)

_____

_____

22. 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; use Serious Adverse Event Report (AN) to report serious and unexpected adverse events or call the DCC if unsure what to do:*

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.*

23. Date event resolved *(enter n if event is not yet resolved):*

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

24. What action was taken:

_____

_____

_____

_____

_____

_____

25. Other comments on event:

_____

_____

_____

_____

_____

_____

E. Administrative information

26. Clinical Coordinator PIN: ____ ____ ____

27. Clinical Coordinator signature:

_____

28. Study Physician PIN: ____ ____ ____

29. Study Physician signature:

_____

30. Date form reviewed:

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

Key this form and fax the DCC (Attention: Aynur Ünalp-Arida) 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

IR - Liver Imaging Studies Report

Purpose: To record liver imaging study results.
When: Visits s2, f024, f048, f096, f144, and f192.
Administered by: Clinical Coordinator.
Instructions: Complete this form at each of the visits listed above if the Baseline Medical History (BG) or Followup Medical History (HI) form says that 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 year prior to screening (visit s2) 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. Liver imaging studies available at baseline and during followup should be reported on this form even if the patient has definite NAFLD or cryptogenic cirrhosis by histology.

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 1

B. Upper abdominal ultrasound

8. Did the patient have an upper abdominal ultrasound in the past year *(screening)*/ since the last visit *(followup)*:

Yes (1) No (2)

11.

9. Date of most recent upper abdominal ultrasound:
____ ____–____ ____ ____–____ ____
day mon year

10. Findings suggestive of NAFLD, cryptogenic 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 year *(screening)*/ since the last visit *(followup)*:

Yes (1) No (2)

14.

12. Date of most recent upper abdominal CT scan:

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

13. Findings suggestive of NAFLD, cryptogenic 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 year *(screening)*/since the last visit *(followup*:

Yes (1) No (2)

17.

15. Date of most recent upper abdominal MRI:

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

16. Findings suggestive of NAFLD, cryptogenic 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

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 s1. If more than one LD form is needed, use visit code "n" on the second LD form.
Administered by: Clinical Coordinator.
Respondent: Patient, 18 years of age or older, without help from spouse or family.
Instructions: 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 #15, 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 #16, 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 1

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	No
(1)	(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	No
(1)	(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

Keyed: ( )

NAFLD Database LP – Symptoms of Liver Disease (Children)

Purpose: To obtain the patient's view of his/her liver disease symptoms.
When: Visits s1, f048, f096, f144, and f192.
Administered by: Self-administered (age 13-17), interviewer administered (age 2-12). Clinical Coordinator must be available to answer questions and review for completeness.
Respondent: Patient, age 2 through 17. Patient age 13 or older should complete the form without help from family. Clinical Coordinator/parent should assist patient age 2-12.
Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-4. If the form is self-administered by the patient, the patient should meet with the Clinical Coordinator, be trained in the completion of the form, and then should complete pages 2-4. 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 2-4 and the Clinical Coordinator should then complete section B below.

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: **l p 1**

7. Study: NAFLD Database 1

B. Administrative information

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

8. How was the questionnaire completed:

Self-administered by patient/parent (1)
→ **10.**
Interview in English (2)
Interview with translator (3)

9. Who was the respondent *(check all that apply)*:

a. Patient: (1)
b. Patient's mother or female guardian: (1)
c. Patient's father or male guardian: (1)
d. Other *(specify)*: (1)

_____
specify

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

_____

11. Date form reviewed:

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

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

Symptoms of Liver Disease

Instructions: People with liver disease may or may not have symptoms, such as pain over the liver area (under your ribs, right of your belly), feeling sick to your stomach, poor appetite (not feeling hungry), itching, or tiredness. In this questionnaire, we are trying to identify what symptoms you have, how severe they are, and how much they affect you.

(Items 1-11 are reserved for clinical center use.)

12. During the last month, how much have you been bothered by the following:

Circle one for each symptom

	Degree of bother				
	None at all	**A little bit**	**Medium**	**Quite a bit**	**Extremely**
a. Pain over liver (pain under ribs, right of your belly)	1	2	3	4	5
b. Nausea (sick to stomach)	1	2	3	4	5
c. Poor appetite (not hungry)	1	2	3	4	5
d. Fatigue	1	2	3	4	5
e. Weight loss	1	2	3	4	5
f. Diarrhea (watery poop)	1	2	3	4	5
g. Muscle aches or cramps	1	2	3	4	5
h. Muscle weakness	1	2	3	4	5
i. Headaches	1	2	3	4	5
j. Easy bruising ("black and blue" marks are easy to get)	1	2	3	4	5
k. Itching	1	2	3	4	5
l. Irritability (get mad easily)	1	2	3	4	5
m. Depression/sadness	1	2	3	4	5
n. Trouble sleeping	1	2	3	4	5
o. Trouble concentrating (trouble with attention, thinking about one thing at a time)	1	2	3	4	5

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

Circle one for each symptom

Degree of bother

	None at all	A little bit	Medium	Quite a bit	Extremely
p. Jaundice (yellow color to skin, eyes, etc)	1	2	3	4	5
q. Dark urine (dark pee)	1	2	3	4	5
r. Swelling of ankles	1	2	3	4	5
s. Swelling of abdomen (belly swells up)	1	2	3	4	5

13. Which of the following best describes how tired you feel and how your tiredness affects you *(choose only one)*:

Circle one

I feel normal and am not tired **(If this is how you feel, please circle "1" and go to item number 17 – Thank you!)** 1
I feel tired some of the time, but can do what I want to do without trouble 2
I feel tired, and do what I want but with trouble 3
I feel tired and it keeps me from doing what I want to do 4

14. How often are you bothered by being tired *(choose only one)*:

All day, every day 1
Part of the day, every day 2
At least part of several days a week 3
At least part of one day a week 4
Not as much as above 5

15. Are you tired *(choose only one)*:

When you wake up in the morning 1
Or does it come on with the day 2
Or does it have no time pattern 3

16. Do you feel more tired the day after you exercise or have a lot of activity:

Yes 1
No 2

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

17. In general, how have you felt overall in the past month:

Very good 1
Good 2
Fair 3
Poor 4
Awful 5

18. Today's date:

_____

Thank you for completing this questionnaire.

NAFLD Database

LQ – Symptoms of Liver Disease

Purpose: To obtain the patient's view of his/her liver disease symptoms.
When: Visits s1, f048, f096, f144, and f192.
Administered by: Self-administered during the visit, but Clinical Coordinator must be available to answer questions and review for completeness.
Respondent: Patient, 18 years of age or older.
Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-4. The patient should complete pages 2-4 during the visit. 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 2-4 and the Clinical Coordinator should then complete section B below.

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: **l q 1**

7. Study: NAFLD Database 1

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

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

9. Date form reviewed:

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

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

Symptoms of Liver Disease

Instructions: People with liver disease may or may not have symptoms, such as pain over the liver area (right upper quadrant), nausea, poor appetite, itching, tiredness, or fatigue. In this questionnaire, we are trying to identify what symptoms you have, how severe they are, and how much they affect your life style.

(Items 1-9 are reserved for clinical center use.)

10. During the last month, how much have you been bothered by the following:

Circle one for each symptom

	Degree of bother				
	None at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
a. Pain over liver (right upper quadrant)	1	2	3	4	5
b. Nausea	1	2	3	4	5
c. Poor appetite	1	2	3	4	5
d. Fatigue	1	2	3	4	5
e. Weight loss	1	2	3	4	5
f. Diarrhea	1	2	3	4	5
g. Muscle aches or cramps	1	2	3	4	5
h. Muscle weakness	1	2	3	4	5
i. Headaches	1	2	3	4	5
j. Easy bruising	1	2	3	4	5
k. Itching	1	2	3	4	5
l. Irritability	1	2	3	4	5
m. Depression/sadness	1	2	3	4	5
n. Trouble sleeping	1	2	3	4	5
o. Trouble concentrating	1	2	3	4	5
p. Jaundice (yellow color to skin, eyes, etc)	1	2	3	4	5
q. Dark urine	1	2	3	4	5
r. Swelling of ankles	1	2	3	4	5
s. Swelling of abdomen	1	2	3	4	5

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

11. Which of the following best describes your level of fatigue and the effects of your fatigue *(choose only one)*:

	Circle one
I feel completely normal and have no fatigue **(circle "1" and go to item # 16)**	1
I have some fatigue, but I can do what I want to do without difficulty	2
I have fatigue, and I do what I want to do but with difficulty	3
I have fatigue and it keeps me from doing what I want to do	4
I have fatigue that prevents me from working	5
I have fatigue that prevents me from working and requires that I have assistance to carry out normal activities of living	6
I am worse off than any of these statements suggest	7

12. How frequently are you bothered by fatigue *(choose only one)*:

All day, every day	1
Part of the day, every day	2
At least part of several days a week	3
At least part of one day a week	4
Less frequently	5

13. Is your fatigue typically present *(choose only one)*:

When you wake up in the morning	1
Or does it come on with the day	2
Or does it have no time pattern	3

14. Is your fatigue typically worse the day after a period of extra activity or exercise:

Yes	1
No	2

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

15. Do you believe that your fatigue is due to your liver problem (as opposed to something else, like not getting enough sleep, depression or being out of shape):

Circle one

Yes 1
No 2

16. In general, how have you felt overall in the past month:

Very good 1
Good 2
Fair 3
Poor 4
Awful 5

17. Today's date:

_____

Thank you for completing this questionnaire.

NAFLD Database

LR - Laboratory Results - Tests Done During Screening and Followup

Purpose: To record archival and current laboratory test results for tests done during both screening and followup.
When: Visits s2, f048, f096, f144, and f192.
Administered by: Study Physician (adult hepatologist, pediatric hepatologist, or pediatrician) and Clinical Coordinator.
Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test 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 a calculator if you need to convert units to match the units specified on this form. Please note that the units 10^3 cells/μL, 1000 cells/μL, and 10^9 cells/L are equivalent. 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.

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: ____ ____ ____ ____

6. Form & revision: 1 r 3

7. Study: NAFLD Database 1

B. Hematology

8. Date of blood draw for complete blood count:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).

9. Hemoglobin: ____ ____ • ____ ____
g/dL

10. Hematocrit: ____ ____ • ____ ____
%

11. White blood cell count (WBC):

____ ____ ____ • ____ ____
10^3 cells/μL or 10^9 cells/L

12. Platelet count:

____,____ ____ ____,____ ____ ____
cells/ μL

C. Chemistries and HbA1c

13. Date of blood draw for chemistries:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).

14. Sodium:* ____ ____ ____
mEq/L

15. Potassium:* ____ ____ • ____
mEq/L

16. Chloride:* ____ ____ ____
mEq/L

17. Bicarbonate:* ____ ____ • ____
mEq/L

18. Calcium:* ____ ____ • ____
mg/dL

19. Phosphate:* ____ ____ • ____
mg/dL

20. Blood urea nitrogen (BUN): ____ ____
mg/dL

21. Creatinine: ____ ____ • ____
mg/dL

22. Uric acid: ____ ____ • ____
mg/dL

** Optional: If not done, enter "m".*

23. 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 followup visit (check the patient's Database visit time window guide).

24. HbA1c: ____ ____ • ____ ____ %

D. Liver panel and alpha feto protein

25. Date of blood draw for liver panel:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).

26. Bilirubin (total): ____ ____ • ____ ____ mg/dL

27. Bilirubin (direct): ____ ____ • ____ ____ mg/dL

28. Aspartate aminotransferase (AST)

____ ____ ____ ____ U/L

a. Upper limit of normal: ____ ____ ____ ____ U/L

b. Lower limit of normal: ____ ____ ____ U/L

29. Alanine aminotransferase (ALT)

____ ____ ____ ____ U/L

a. Upper limit of normal: ____ ____ ____ ____ U/L

b. Lower limit of normal: ____ ____ ____ U/L

30. Alkaline phosphatase ____ ____ ____ ____ U/L

a. Upper limit of normal: ____ ____ ____ ____ U/L

b. Lower limit of normal: ____ ____ ____ U/L

31. Gamma glutamyl transferase (GGT):

____ ____ ____ U/L

32. Total protein: ____ ____ • ____ ____ g/dL

33. Albumin: ____ ____ • ____ ____ g/dL

34. Prothrombin time (PT): ____ ____ • ____ ____ sec

35. International normalized ratio (INR):

____ ____ • ____ ____

36. Date of blood draw for alpha feto protein:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide). Record "m" if test not done.

37. Alpha feto protein:

____ ____ ____ ____ • ____ ____ ____ ng/mL

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.

38. Date of blood draw for fasting lipid profile:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database 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.

39. Date of blood draw for fasting glucose and insulin levels:

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

Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).

a. Serum glucose: ____ ____ ____ mg/dL

b. Serum insulin: ____ ____ ____ • ____ μU/mL

G. Administrative information

40. Study Physician PIN: ____ ____ ____

41. Study Physician signature:

_____

42. Clinical Coordinator PIN: ____ ____ ____

43. Clinical Coordinator signature:

_____

44. Date form reviewed:

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

NAFLD Database

LS - Laboratory Results - Tests Done only During Screening

Purpose: To record archival and current results of laboratory tests done only at screening.

When: Visit s1.

Administered by: Study Physician (adult hepatologist or pediatrician) and Clinical Coordinator.

Instructions: 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. If EHg is checked for any item, you do not need to complete the rest of the form and the form may 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: s 1 ____ ____

6. Form & revision: 1 s 1

7. Study: NAFLD Database 1

B. Screening etiologic tests

8. 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. *Record as ''m'' if test is not done.*

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)

c. Hepatitis B surface antibody (anti-HBs)*:
Positive (1)
Negative (2)

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) EHg ____
Negative (2)
Not available (3)

f. Hepatitis A virus antibody (anti-HAV, total):
Positive (1)
Negative (2)
Not available (3)

C. Iron

9. 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

10. Is hepatic iron index available:

(Yes 1) (No 2)

12.

11. Hepatic iron index: ____ ____ • ____

µMo1/g/year

D. HFE gene analysis

12. 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)

15.

13. Date of blood draw for HFE gene analysis:

____ ____–____ ____ ____–____ ____

day mon year

14. 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

15. Is patient 40 years old or younger:

(Yes 1) (No 2)

18.

16. 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.

17. Ceruloplasmin ____ ____ • ____

mg/dL

a. Upper limit of normal: ____ ____ • ____

mg/dL

b. Lower limit of normal: ____ ____ • ____

mg/dL

F. Alpha-1 antitrypsin

18. Date of blood draw for alpha-1 antitrypsin (A1AT):

____ ____–____ ____ ____–____ ____

day mon year

Repeat if date is greater than 10 years prior to screening.

19. Alpha-1 antitrypsin (A1AT) ____ ____ ____

mg/dL

a. Upper limit of normal: ____ ____ ____

mg/dL

b. Lower limit of normal: ____ ____ ____

mg/dL

20. A1AT phenotype *(if unknown record as ''m'')*

a. Pi Z heterozygote:

(Yes 1) (No 2)

b. Pi ZZ homozygote:

(Yes 1) (No 2)

21. A1AT deficiency *(physician judgment):*

(Yes 1) (No 2)

Elig

G. Autoantibody studies

22. Date of blood draw for autoantibody tests:

____ ____–____ ____ ____–____ ____

day mon year

Repeat if date is greater than 5 years prior to screening.

23. Antinuclear antibody (ANA):

Positive	(*1)
Negative	(2)

24.

a. If positive, ANA: 1/ ____ ____ ____ ____

**If results are given as units, record as ''n,'' and key the actual result in the General Comments.*

24. Antismooth muscle antibody (ASMA):

Positive (*1)
Negative (2)
25.

a. If positive, ASMA: 1/ ____ ____ ____ ____

**If results are given as units, record as ''n,'' and key the actual result in the General Comments.*

25. Antimitochondrial antibody (AMA)*:

Positive (†1)
Negative (2)
26.

a. If positive, AMA: 1/ ____ ____ ____ ____

**Optional if patient under age 18, enter ''m'' if not done.*

†If results are given as units, record as ''n,'' and key the actual result in the General Comments.

26. Is the patient 18 or older:

Yes (1) No (2)
30.

27. Lymphocytotoxic antibody (LCA)*:

Positive (1)
Negative (2)
28.

a. If positive, LCA: 1/ ____ ____ ____ ____

28. Antibody to liver-kidney microsomal antigen (LKM1)*:

Positive (1)
Negative (2)
29.

a. If positive, LKM1: 1/ ____ ____ ____ ____

29. Rheumatoid factor (RF)*:

Positive (1)
Negative (2)
30.

a. If positive, RF: ____ ____ ____ ____

**Optional - record as ''m'' if test is not done*

H. Immunoglobulin levels

30. Are immunoglobulin levels available:

Yes (1) No (2)
35.

31. Date of blood draw for immunoglobulin levels:

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

32. IgA: ____ ____ ____ mg/dL

33. IgG: ____ ____ ____ ____ mg/dL

34. IgM: ____ ____ ____ mg/dL

I. Other screening blood tests

35. 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.*

36. Thyroid stimulating hormone:

____ ____ • ____ ____ μU/mL

J. 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

Keyed: ( )

NAFLD Database

MA - Modifiable Activity Questionnaire

Purpose: To obtain the patient's physical activity.
When: Visits s2, f048, f096, f144, and f192.
Administered by: Interview administered or self-administered, depending on the age of the patient. Parents may assist with completion, if needed. Clinical Coordinator must be available at visits to answer questions and to review completed forms.
Respondent: Patient, age 8-17.
Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-3. The patient should meet with the interviewer, be trained in completion of the form, and then should complete pages 2-3. If needed, the Clinical Coordinator may administer the interview to the patient. 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 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 month year

5. Visit code: ____ ____ ____ ____

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

7. Study: NAFLD Database 1

B. Administrative information

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

8. How was the questionnaire completed:
Self-administered by patient/parent (1)
10.
Interview in English (2)
Interview with translator (3)

9. Who was the respondent *(check all that apply)*
a. Patient: (1)
b. Patient's mother or female guardian: (1)
c. Patient's father or male guardian: (1)
d. Other, *specify*: (1)
_____

10. Clinical Coordinator
a. PIN: ____ ____ ____

b. Signature: _____

11. Date form reviewed:

____ ____ - ____ ____ ____ - ____ ____
day month year

Affix Label Here
Patient ID: __ __ __ __
Patient code: __ __ __
Visit code: __ __ __ __

Modifiable Activity Questionnaire

(Items 1-11 are reserved for clinic use.)

12. How many times in the past 14 days have you done at least 20 minutes of exercise hard enough to make you breathe heavily and make your heart beat fast? (Hard exercise includes, for example, playing basketball, jogging, or fast bicycling; include time in physical education class)?

Circle one

None 1
1 to 2 days 2
3 to 5 days 3
6 to 8 days 4
9 or more days 5

13. How many times in the past 14 days have you done at least 20 minutes of light exercise that was not enough to make you breathe heavily and make your heart beat fast? (Light exercise includes playing basketball, walking or slow bicycling; include time in physical education class)?

Circle one

None 1
1 to 2 days 2
3 to 5 days 3
6 to 8 days 4
9 or more days 5

14. During a normal week how many hours a day do you watch television and videos, or play computer or video games, or use the computer for other activities before or after school?

Circle one

None 1
1 hour or less 2
2 to 3 hours 3
4 to 5 hours 4
6 or more hours 5

15. During the past 12 months, how many team or individual sports or activities did you participate in on a competitive level, such as varsity or junior varsity sports, intramurals, or out-or-school programs?

Circle one

None 1
1 activity 2
2 activities 3
3 activities 4
4 or more activities 5

What activities did you compete in?

_____

_____

_____

Affix Label Here
Patient ID: __ __ __ __
Patient code: __ __ __
Visit code: __ __ __ __

PAST YEAR LEISURE-TIME PHYSICAL ACTIVITY

16. Check all activities that you did at least 10 times in the **PAST YEAR**. Do not include time spent in school physical education classes. Include all sport teams that you participated in during the last year.

( ) 01. Aerobics
( ) 02. Band/Drill Team
( ) 03. Baseball
( ) 04. Basketball
( ) 05. Bicycling
( ) 06. Bowling
( ) 07. Cheerleading
( ) 08. Dance Class
( ) 09. Football
( ) 10. Garden/Yard Work
( ) 11. Gymnastics
( ) 12. Hiking
( ) 13. Ice Skating
( ) 14. Roller Skating
( ) 15. Running and Exercise
( ) 16. Skateboarding
( ) 17. Snow Skiing
( ) 18. Soccer
( ) 19. Softball
( ) 20. Street Hockey
( ) 21. Swimming
( ) 22. Tennis
( ) 23. Volleyball
( ) 24. Water Skiing
( ) 25. Weight Training (Competitive)
( ) 26. Wrestling
( ) 27. Others: ____________________
____

List each activity that you checked above in the "Activity" box below.
Check the months you did each activity and then estimate the amount of time spent in each activity.

Activity Code #	Activity	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	Months per Year	Days per Week	Minutes per Day
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __
__ __														__ __	__	__ __ __

17. Today's date: ________________________________

NAFLD Database

MV - Missed or Incomplete Visit

Purpose: Record reason(s) for missed or incomplete visit.
When: At the close of a visit window for any missed followup visit or for any followup visit with specific forms not completed. Use visit code f024, f048, f096, f144, or f192.
Respondent: None.
Completed by: Clinical Coordinator.
Instructions: Complete this form when a patient fails to complete a visit or specific visit procedures (resulting in missing forms) within the time window for the visit.

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: f ____ ____ ____

6. Form & revision: m v 1

7. Study: NAFLD Database 1

B. Reason for completion of this form

8. Was the entire visit missed:

(Yes 1) (No 2)

11.

C. Missed visit information

9. Reason for missed visit *(check all that apply)*

a. Patient was ill: (1)

b. Patient was temporarily away from area: (1)

c. Patient refused to return: (1)

d. Patient has permanently moved from the area: (1)

e. Unable to contact patient: (1)

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

_____
specify

10. Steps taken to avoid missing the visit *(check all that apply)*

a. Telephoned patient: (1)

b. Mailed reminder card: (1)

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

_____
specify

14.

D. Missed form information

11. Check form(s) not completed
(check required forms that were missed)

a. Food Questionnaire Documentation (BD): (1)

b. Blood Processing for Plasma and Serum (BP): (1)

c. Followup Medical History (HI): (1)

d. Liver Imaging Studies Report (IR): (1)

e. Symptoms of Liver Disease (Children) (LP): (1)

f. Symptoms of Liver Disease (LQ): (1)

g. Laboratory Results - Tests Done During Screening and Followup (LR): (1)

h. Modifiable Activity Questionnaire (MA): (1)

i. Physical Activity (PA): (1)

j. Physical Examination (PE): (1)

k. Focused Physical Examination (PF): (1)

l. Pediatric Quality of Life: Parent of adolescent age 13-17 (PQ): (1)

m. Pediatric Quality of Life: Parent of child age 8-12 (PR): (1)

n. Pediatric Quality of Life: Parent of child age 5-7 (PS): (1)

o. Pediatric Quality of Life: Parent of toddler (PT): (1)

p. Pediatric Quality of Life: Child age 5-7 (PV): (1)

q. Pediatric Quality of Life: Child age 8-12 (PW): (1)

r. Pediatric Quality of Life: Adolescent age 13-17 (PY): (1)

s. MOS 36-Item Short-form Health Survey (QF): (1)

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

_____
specify

12. Reason form(s) not completed
(check all that apply)

a. Patient was ill: (1)

b. Patient refused procedure: (1)

c. Parent refused procedure: (1)

d. Procedure forgotten: (1)

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

_____
specify

13. Attempts made to complete form(s) *(check all that apply)*

a. Attempted to reschedule procedure: (1)

b. Attempted to collect interview data by phone from patient/family: (1)

c. Attempted to gain patient/parent cooperation: (1)

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

_____
specify

E. Administrative information

14. Clinical Coordinator PIN: ___ ___ ___

15. Clinical Coordinator signature:

_____

16. Date form reviewed:

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

NAFLD Database

PA – Physical Activity

Purpose: To obtain the patient's physical activity.
When: Visits s2, f048, f096, f144, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and review completed forms.
Respondent: Patient, 18 years of age or older, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A below and attach a label to each of pages 2-4.
Screening: The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-4. 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 2-4 and the Clinical Coordinator should complete section B below. **Followup:** Pages 2-4 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B. Item 4 should be completed with the date the patient wrote in item 39. If the patient did not write in a date, use the date of the study visit for the visit date.

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: **p a 1**

7. Study: NAFLD Database 1

B. Administrative information

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

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

_____

9. Date form reviewed:

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

Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

PA - Physical Activity

Instructions: This survey asks for your views about your physical activity. *(Items 1-9 are reserved for clinical center use).*

C. Non-Recreational Activity (Work Related)

The following questions are about your non-recreational activity. Non-recreational activity is what you consider your main day to day activity, at work or at home, whether you get paid or not.

Circle one

10. Level of activity that best describes your usual non-recreational activity.

Vigorous or strenuous activity: 1
(involves heavy lifting, digging, handling heavy tools or equipment, or any other activity causing you to work up a sweat or get out of breath)

Moderate activity: 2
(requires moderate-paced walking on a flat surface, heavy one-arm work or moderate two-arm work, such as picking, sweeping, lifting light objects, or heavy housework)

Light activity: 3
(involves sitting down with one hand movement, moderate one-arm work or light two-arm work, with occasional walking or standing such as office work, filing or sorting, or light or moderate housework)

11. On average, how many hours per day do you spend at this level of activity?

____ ____ Hours

12. On average, how many hours per day do you spend sitting down?

____ ____ Hours

D. Recreational Activity (Non-Work Related)

The following questions are about the recreational activities you spend at least 15 minutes doing each week. You should count walking or biking to work and any other activities outside of work. Next to each activity that you participate in, write in how many total hours or minutes you do that activity on an average week. Mark the places for hours and minutes only for the activities you participate in.

For each activity that you engage in for at least 15 minutes per week, please circle the activity and write the number of hours or minutes that you do that activity per week.	
13. Swimming	Hours: _____ _____ Minutes: _____ _____
14. Jogging	Hours: _____ _____ Minutes: _____ _____
15. Running	Hours: _____ _____ Minutes: _____ _____
16. Brisk walking	Hours: _____ _____ Minutes: _____ _____
17. Bicycling on hills	Hours: _____ _____ Minutes: _____ _____
18. Bicycling on flat surfaces	Hours: _____ _____ Minutes: _____ _____
19. Hiking or climbing	Hours: _____ _____ Minutes: _____ _____
20. Yard work / Gardening	Hours: _____ _____ Minutes: _____ _____
21. Aerobics	Hours: _____ _____ Minutes: _____ _____
22. Dancing	Hours: _____ _____ Minutes: _____ _____
23. Calisthenics (exercises without machines)	Hours: _____ _____ Minutes: _____ _____
24. Weight lifting, using weight machines, or heavy lifting	Hours: _____ _____ Minutes: _____ _____
25. Treadmill or Stairmaster	Hours: _____ _____ Minutes: _____ _____
26. Chopping wood	Hours: _____ _____ Minutes: _____ _____

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

For each activity that you engage in for at least 15 minutes per week, please circle the activity and write the number of hours or minutes that you do that activity per week.	
27. Painting / Woodworking	Hours: _____ _____ Minutes: _____ _____
28. Housecleaning	Hours: _____ _____ Minutes: _____ _____
29. Golfing	Hours: _____ _____ Minutes: _____ _____
30. Singles tennis, racquetball, or other court sports	Hours: _____ _____ Minutes: _____ _____
31. Doubles tennis, racquetball or other court sports	Hours: _____ _____ Minutes: _____ _____
32. Basketball	Hours: _____ _____ Minutes: _____ _____
33. Football, soccer, or other field sports	Hours: _____ _____ Minutes: _____ _____
34. Skiing	Hours: _____ _____ Minutes: _____ _____
35. Bowling	Hours: _____ _____ Minutes: _____ _____
Others *(write in the name of activity)*:	
36. Name of activity _____	Hours: _____ _____ Minutes: _____ _____
37. Name of activity _____	Hours: _____ _____ Minutes: _____ _____
38. Name of activity _____	Hours: _____ _____ Minutes: _____ _____

39. Today's date:

_____

Thank you for completing this survey. Please bring this completed survey with you to your scheduled NASH CRN study visit.

NAFLD Database

PE - Physical Examination

Purpose: Record detailed physical exam findings.
When: Visits s1, f048, f096, f144, and f192.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient.
Instructions: Details of the protocol for height, weight, waist and hip measurements are found in NAFLD Database SOP, Part I. In brief: Height, weight, waist and hips all 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 in (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other. Skin fold and mid-upper arm circumference should be measured on the right arm with the elbow extended and the arm relaxed. Repeat skin fold measurements until you have two measurements within 10 mm of each other. Repeat mid-upper arm circumference measurements until you have two within 1.5 in (3.8 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: ____ ____ ____ ____

6. Form & revision: p e 2

7. Study: NAFLD Database 1

B. Measurements

8. Height *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)
Centimeters (2)

9. Weight *(shoes off)*

a. Weight, 1st measurement:

____ ____ ____ • ____

b. Weight, 2nd measurement:

____ ____ ____ • ____

c. Units:

Pounds (1)
Kilograms (2)

10. Waist *(standing, at midpoint between highest point of iliac crest and lowest part of costal margin; repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. Circumference, 1st measurement:

____ ____ ____ • ____
waist circumference

b. Circumference, 2nd measurement:

____ ____ ____ • ____
waist circumference

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 in (10.2 cm) of each other)*

a. Circumference, 1st measurement:

____ ____ ____ • ____
hip circumference

b. Circumference, 2nd measurement:

____ ____ ____ • ____
hip circumference

c. Units:

Inches (1)
Centimeters (2)

12. Triceps *(right arm, with elbow extended and arm relaxed; repeat skin fold measurements until you have two within 10 mm of each other; repeat mid-upper arm circumference measurements until you have two within 1.5 in (3.8 cm) of each other)*

a. Skin fold, 1st measurement:

____ ____ ____ • ____
mm

b. Skin fold, 2nd measurement:

____ ____ ____ • ____
mm

c. Mid-upper arm circumference, 1st measurement:

____ ____ • ____
arm circumference

d. Mid-upper arm circumference, 2nd measurement:

____ ____ • ____
arm circumference

e. Units for arm circumference:

Inches (1)
Centimeters (2)

13. Temperature
(Oral or other, as appropriate for age)

a. Degrees: ____ ____ ____ • ____

b. Scale:

Fahrenheit (1)
Centigrade (2)

14. Blood pressure

a. Systolic: ____ ____ ____
mmHg

b. Diastolic: ____ ____ ____
mmHg

15. Resting radial pulse: ____ ____ ____
beats/minute

16. Respiratory rate: ____ ____
breaths/minute

C. Examination findings

17. Skin:

Normal (1)

20.

Abnormal (2)

18. Acanthosis nigricans *(check only one):*

Absent *(not detectable on close inspection)* (0)

Present *(clearly present on close inspection, not visible to casual observer, extent not measurable)* (1)

Mild *(limited to base of skull, not extending to lateral margins of neck, < 3 inches in breadth)* (2)

Moderate *(extending to lateral margins of neck, 3-6 inches in breadth, not visible from patient's front)* (3)

Severe *(extending anteriorly, > 6 inches in breadth, visible from front)* (4)

19. Other skin abnormality *(check all that apply)*

a. Jaundice: (1)
b. Palmar erythema: (1)
c. Spider angiomata: (1)
d. Other *(specify):* (1)

_____

e. None of the above: (1)

20. Head, eyes, ears, nose, throat:

Normal (1)

22.

Abnormal (2)

21. Abnormality of the head, eyes, nose, throat
(check all that apply)

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

_____
specify

22. Neck:

Normal (1)

23.

Abnormal (2)

_____
specify abnormality

23. Lymphatic:

Normal (1)
24. ____
Abnormal (2)

_____
specify abnormality

24. Chest and lungs:

Normal (1)
25. ____
Abnormal (2)

_____
specify

25. Heart:

Normal (1)
26. ____
Abnormal (2)

_____
specify abnormality

26. Abdomen:

Normal (1)
28. ____
Abnormal (2)

27. Abdomen abnormality
(check all that apply)

a. Ascites: (1)
b. Obese: (1)
c. Other *(specify):* (1)

_____
specify

28. Liver and spleen:

Normal (1)
30. ____
Abnormal (2)

29. Abnormality of liver or spleen *(check all that apply)*

a. Hepatomegaly: (1)
(if checked, span from right midclavicular line):
____ ____ • ____
cm

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

_____
specify

30. Extremities:

Not performed (0)
32. ____
Normal (1)
32. ____
Abnormal (2)

31. Abnormality of the extremities
(check all that apply)

a. Contractures: (1)
b. Muscle wasting: (1)
c. Palmar erythema: (1)
d. Pedal edema: (1)
e. Other *(specify):* (1)

_____
specify

32. Genitourinary/pelvis:

Not performed (0)
33. ____
Normal (1)
33. ____
Abnormal (2)

_____
specify

33. Nervous system:

Not performed (0)
35. ____
Normal (1)
35. ____
Abnormal (2)

34. Abnormality of the nervous system *(check all that apply):*

a. Mental status abnormal: (1)

b. Asterixis: (1)

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

_____
specify

D. Tanner Staging

35. Is Tanner staging required for this participant *(Note: Required at screening visit if participant is 17 years old or younger.) (check only one):*

Yes, participant has not reached full sexual maturity or is 17 years old or younger: (1)

No, participant is 18 years old or older (2)

44. ____

No, participant had reached full sexual maturity *(Tanner stage 5 on all parameters at screening or for 2 consecutive visits)* (3)

44. ____

36. Is the patient female:

Yes (1) No (2)

40. ____

Male Tanner Staging

37. Genital stage: ____ (1-5)

38. Testicular volume *(smallest of right and left):* ____ ____ cc

39. Pubic hair stage: ____ (1-5)

44. ____

Female Tanner Staging

40. Breast stage: ____ (1-5)

41. Pubic hair stage: ____ (1-5)

42. Has menarche occurred:

Yes (1) No (2)

44. ____

43. What was the participant's age at menarche:

____ ____
age in years

E. Administrative information

44. Study Physician PIN: ____ ____ ____

45. Study Physician signature:

_____

46. Clinical Coordinator PIN: ____ ____ ____

47. Clinical Coordinator signature:

_____

48. Date form reviewed:

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

NAFLD Database

PF - Focused Physical Examination

Purpose: Record focused physical exam findings.
When: Visit f024.
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 SOP Part 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 in (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 in (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: f 0 2 4

6. Form & revision: p f 2

7. Study: NAFLD Database 1

B. Measurements

8. Height *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)
Centimeters (2)

9. Weight *(shoes off)*

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 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)

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. Focused liver signs

16. Abnormality *(check all that apply)*

a. Ascites: (1)
b. Asterixis: (1)
c. Contractures: (1)
d. Hepatic encephalopathy: (1)
e. Hepatocellular carcinoma: (1)
f. Hepatomegaly: (1)

If Yes, span from right midclavicular line:

____ ____ • ____ cm

g. Hepatopulmonary syndrome: (1)
h. Hepatorenal syndrome: (1)
i. Jaundice: (1)
j. Muscle wasting: (1)
k. Palmar erythema: (1)
l. Pedal edema: (1)
m. Portal hypertension: (1)
n. Spider angiomata: (1)
o. Splenomegaly: (1)
p. Other, *(specify):* (1)

_____

q. None of the above (1)

D. 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

RG - Registration

Purpose: To register patients as candidates for enrollment in NAFLD Database and to assign a patient ID number. This is the first form completed for a NAFLD Database patient. The Registration Form must be the first form keyed, before any other NAFLD Database forms.

When: At first screening visit (s1).

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: s 1 ____ ____

6. Form & revision: r g 1

7. Study: NAFLD Database 1

B. Consent

8. Has the patient (or patient's guardian) signed the NAFLD Database 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)

23. Is the patient under age 18:

(Yes 1) (No 2)

28. ___

24. Current age of patient's mother, stepmother, or female guardian *(show patient/parent Flash Card #7; check only one):*

- Not applicable (mother is deceased or patient has no stepmother or female guardian) (0)
- 19 or younger (1)
- 20-29 years (2)
- 30-39 years (3)
- 40-49 years (4)
- 50-59 years (5)
- 60 years or older (6)

25. Highest educational level achieved by patient's mother, stepmother, or female guardian *(show patient/parent Flash Card #8; if education of mother or female guardian is unknown, record as "n"; check only one):*

- Never attended school (0)
- Did not complete high school (1)
- Completed high school (2)
- Some college or post high school education or training (3)
- Bachelor's degree or higher (4)

26. Current age of patient's father, stepfather, or male guardian *(show patient/parent Flash Card #7; check only one):*

Not applicable (father is deceased or patient has no stepfather or male guardian)	(0)
19 or younger	(1)
20-29 years	(2)
30-39 years	(3)
40-49 years	(4)
50-59 years	(5)
60 years or older	(6)

27. Highest educational level achieved by patient's father, stepfather, or male guardian *(show patient/parent Flash Card #8; if education of father or male guardian is unknown, record as "n"; check only one):*

Never attended school	(0)
Did not complete high school	(1)
Completed high school	(2)
Some college or post high school education or training	(3)
Bachelor's degree or higher	(4)

D. Source of patient

(clinic staff should pick the best description of the source of the patient)

28. Source of patient *(check only one):*

Bariatric surgery clinic	(01)
Current patient of NASH CRN investigator	(02)
Diabetes clinic	(03)
GI/liver clinic	(04)
HMO-based	(05)
Internal medicine clinic	(06)
Lipid disorders clinic	(07)
Liver transplant clinic	(08)
Obesity clinic	(09)
Pediatric clinic	(10)
Pediatric weight disorders clinic	(11)
Primary care clinic	(12)
Self referral	(13)
Other, *(specify):*	(14)

_____
specify

E. Previous registration in a NASH CRN study

29. Has the patient ever been assigned an ID number in a NASH CRN study:

Yes (1) No (2)

33. ⌊__

30. In which NASH CRN studies has the patient previously been registered *(check all that apply)*

a. PIVENS:	(1)
b. TONIC:	(1)
c. Other, *(specify):*	(1)

_____
specify

31. ID Number previously assigned to patient *(record patient ID in item 2):*

___ ___ ___ ___

32. Code previously assigned to patient *(record patient code in item 3):*

___ ___ ___

34. ⌊__

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.)

33. Place ID label below and record Patient ID in item 2 and patient code in item 3.

CCCC ####, zzz

G. Administrative information

34. Clinical Coordinator PIN: ___ ___ ___

35. Clinical Coordinator signature:

_____

36. Date form reviewed:

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