

## NAFLD Database 2

AD – Alcohol Use Disorders Identification Test  
(AUDIT)

**Purpose:** To screen for current heavy drinking and/or active alcohol abuse or dependence.

**When:** Screening visit t0.

**Administered by:** Self-administered. Clinical Coordinator must be available at visits to answer questions and review completed forms.

**Respondent:** Patient age 12 or older.

**Instructions:** Flash Card #9, Drink Equivalents, may be used with this form. The Clinical Coordinator should complete section A below and write the patient ID on pages 2-3. The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator then should complete section B below.

**A. Center, patient, and visit identification**

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

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

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day mon year

5. Visit code:  t   0  \_\_\_\_\_

6. Form & revision:  a   d   1

7. Study: NAFLD Database 2  6

**B. Administrative information**

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

8. How was the questionnaire completed:

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

9. Clinical Coordinator

a. PIN: \_\_\_\_\_

b. Signature: \_\_\_\_\_

10. Date form reviewed:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day mon year

**AD – Alcohol Use Disorders Identification Test (AUDIT)**

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

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

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

↳ **21.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**21.** Today's date:

\_\_\_\_\_

**Thank you for completing this questionnaire.**



- 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 )

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

( Yes ( \* 1 ) No ( 2 ) )

**21.** \_\_\_\_\_

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

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

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

**C. NAFLD history**

- 16.** Date patient was first diagnosed with fatty liver disease or NASH-related cirrhosis:
- \_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

- 21.** Will the patient have a biopsy during screening:
- ( Yes ( \* 1 ) No ( 2 ) )

- 17.** What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis (*check all that apply*)
- a.** Symptoms for liver disease: ( 1 )  
**b.** Result of being evaluated for another illness: ( 1 )  
**c.** During a routine or insurance physical examination: ( 1 )  
**d.** Blood donation: ( 1 )  
**e.** Other (*specify*): ( 1 )

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

- 22.** Has the patient had a liver imaging study in the past 6 months:
- ( Yes ( \* 1 ) No ( 2 ) )
- \*Complete the Liver Imaging Studies Report (IR) form.*

\_\_\_\_\_ specify

**D. Weight history**

- 18.** What procedures/tests supported this first diagnosis (*check all that apply*)
- a.** Liver biopsy: ( 1 )  
**b.** Imaging studies (*Ultrasound, CT, MRI*): ( 1 )  
**c.** Elevated aminotransferases: ( 1 )  
**d.** Other (*specify*): ( 1 )

- 23.** What was the patient's birthweight:
- \_\_\_\_\_ lbs \_\_\_\_\_ oz

\_\_\_\_\_ specify

- 24.** Review flashcard 11. Which (picture) best describes your weight pattern over the past 5 years (*check only one*):
- Up and down, up and down ( 1 )  
 Up gradually ( 2 )  
 Up sharply (*gained a lot in a brief interval*) ( 3 )  
 Down gradually ( 4 )  
 Down sharply (*lost a lot in a brief interval*) ( 5 )  
 No or minimal change ( 6 )

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

26. What is the most the patient has ever  
weighed:  
\_\_\_\_\_ lbs

27. At what age did the patient weigh the  
most:  
\_\_\_\_\_ age in years

28. Is the patient age 18 or older:  
 Yes ( 1 )  No ( 2 )  
31.

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

30. At what age did the patient weigh the  
least since age 18:  
\_\_\_\_\_ age in years

31. Does the patient weigh more than he/she  
did one year ago:  
 Yes ( 1 )  No ( 2 )  
33.

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

33. Does the patient weigh less than he/she  
did one year ago:  
 Yes ( 1 )  No ( 2 )  
35.

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

35. Did the patient try to lose or gain weight:  
 Yes ( 1 )  No ( 2 )  
37.

36. Which did the patient try to do (check only one):  
Gain weight ( 1 )  
Lose weight ( 2 )

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

37. Is the patient age 12 or older:  
 Yes ( 1 )  No ( 2 )  
43.

38. Have you ever smoked tobacco cigarettes:  
Never ( 1 )  
In the past but not anymore ( 2 )  
Currently smokes cigarettes ( 3 )  
43.

39. Did you smoke cigarettes regularly ("No" means  
less than 20 packs of cigarettes in a lifetime or less  
than 1 cigarette a day for one year):  
 Yes ( 1 )  No ( 2 )  
43.

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

41. How old were you when you (last)  
stopped smoking cigarettes (code as "n" if the pa-  
tient didn't stop smoking):  
\_\_\_\_\_ years

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

**F. Menstrual history**

43. Is the patient female:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 49.

44. Has menarche occurred:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 49.

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

\_\_\_\_\_  
 age in years

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

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

47. Is patient post-menopausal:

( Yes ) ( No )  
 ( 1 ) ( 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 )
- 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. Glycogen storage disease: ( 1 )

k. Iron overload: ( 1 )

l. Polycystic liver disease: ( 1 )

m. Drug induced liver disease: ( 1 )

n. Gilbert's syndrome: ( 1 )

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

p. Bleeding from varices: ( 1 )

q. Other gastrointestinal bleeding: ( 1 )

r. Ascites: ( 1 )

s. Edema: ( 1 )

t. Hepatic encephalopathy: ( 1 )

u. Portal hypertension: ( 1 )

v. Hepatorenal syndrome: ( 1 )

w. Hepatopulmonary syndrome: ( 1 )

x. Short bowel syndrome: ( 1 )

y. Hemophilia (bleeding disorder): ( 1 )

z. HIV positive: ( 1 )

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

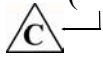
ab. Endocrine disease (hormonal abnormality): ( 1 )

ac. Hepatocellular carcinoma: ( 1 )

ad. Other malignancy (cancer): ( 1 )

ae. Peripheral neuropathy: ( 1 )

- af. Seizure disorder or epilepsy: (  )
- ag. Drug allergies: (  )
- ah. Hypothyroidism: (  )
- ai. Hypertension: (  )
- aj. Cerebrovascular disease: (  )
- ak. Dysbetalipoproteinemia: (  )
- al. Chronic cholestasis: (  )
- am. Hyperlipidemia (*high cholesterol, high triglycerides*): (  )
- an. Pancreatitis: (  )
- ao. Cholelithiasis: (  )
- ap. Coronary artery disease: (  )
- aq. Elevated uric acid such as gout: (  )
- ar. Kidney disease: (  )
- as. Polycystic ovary syndrome: (  )
- at. Sleep apnea (*not breathing during sleep*): (  )
- au. Dermatologic disorders: (  )
- av. Myopathy: (  )
- aw. Myositis: (  )
- ax. Major depression: (  )
- ay. Schizophrenia: (  )
- az. Bipolar disorder: (  )
- ba. Obsessive compulsive disorder: (  )
- bb. Severe anxiety or personality disorder: (  )
- bc. None of the above: (  )



**51. Organ, limb, or bone marrow transplant**

- a. Has the patient ever received a liver transplant:
 

Yes	No
( <input type="checkbox"/> )	( <input type="checkbox"/> )
- b. Has the patient ever received any other organ, limb, or bone marrow transplant:
 

Yes	No
( <input type="checkbox"/> )	( <input type="checkbox"/> )

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

- |                              |                              |
|------------------------------|------------------------------|
| Yes                          | No                           |
| ( <input type="checkbox"/> ) | ( <input type="checkbox"/> ) |



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

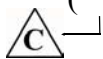
- |                              |                              |
|------------------------------|------------------------------|
| Yes                          | No                           |
| ( <input type="checkbox"/> ) | ( <input type="checkbox"/> ) |

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

- |                              |                              |
|------------------------------|------------------------------|
| Yes                          | No                           |
| ( <input type="checkbox"/> ) | ( <input type="checkbox"/> ) |

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

- a. Stapling or banding of the stomach: (  )
  - b. Jejunioileal (*or other intestinal*) bypass prior to the diagnosis of NAFLD: (  )
  - c. Biliopancreatic diversion: (  )
  - d. Other GI or bariatric surgery (*specify*): (  )
- 
- e. None of the above: (  )





**H. Medication use**

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

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

**56.**

*(If yes, check all that apply):*

- a.** Acarbose (Precose): (  )
- b.** Acetohexamide (Dymelor): (  )
- c.** Chlorpropamide (Diabinese): (  )
- d.** Glimepiride (Amaryl): (  )
- e.** Glipizide (Glucotrol, Glucotrol XL): (  )
- f.** Glyburide (Micronase, DiaBeta, Glynase): (  )
- g.** Insulin: (  )
- h.** Metformin (Glucophage, Glucophage XR): (  )
- i.** Miglitol (Glycet): (  )
- j.** Nateglinide (Starlix): (  )
- k.** Pioglitazone (Actos): (  )
- l.** Repaglinide (Prandin): (  )
- m.** Rosiglitazone (Avandia): (  )
- n.** Tolazamide (Tolinase): (  )
- o.** Tolbutamide (Orinase): (  )
- p.** Other, *(specify)*: (  )
- 

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

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

**57.**

*(If yes, check all that apply):*

- a.** Chlordiazepoxide (Librium): (  )
- b.** Clorazepate dipotassium (Tranxene): (  )
- c.** Diazepam (Valium): (  )
- d.** Disulfiram (Antabuse): (  )
- e.** Hydroxyzine pamoate (Vistaril): (  )
- f.** Naltrexone hydrochloride (Revia): (  )
- g.** Other, *(specify)*: (  )
- 

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

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

**58.**

*(If yes, check all that apply):*

- a.** Atorvastatin (Lipitor): (  )
- b.** Colestipol hydrochloride (Colestid): (  )
- c.** Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (  )
- d.** Gemfibrozil (Gen-Fibro, Lopid): (  )
- e.** Fenofibrate (Tricor): (  )
- f.** Fluvastatin sodium (Lescol): (  )
- g.** Lovastatin (Mevacor): (  )
- h.** Nicotinic acid (Niaspan): (  )
- i.** Pravastatin sodium (Pravachol): (  )
- j.** Rosuvastatin (Crestor): (  )
- k.** Simvastatin (Zocor): (  )
- l.** Other, *(specify)*: (  )
- 

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

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

**59.**

*(If yes, check all that apply):*

- a.** Dexfenfluramine hydrochloride (Redux): (  )
- b.** Fenfluramine hydrochloride (Pondimin): (  )
- c.** Methamphetamine hydrochloride (Desoxyn, Gradumet): (  )
- d.** Orlistat (Xenical): (  )
- e.** Phendimetrazine tartrate (Adipost, Bontril): (  )
- f.** Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine): (  )
- g.** Sibutramine hydrochloride monohydrate (Meridia): (  )
- h.** Other, *(specify)*: (  )
-

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

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

**60.**

*(If yes, check all that apply):*

- a.** Acetaminophen (Tylenol): ( 1 )
- b.** Aspirin - 325 mg: ( 1 )
- c.** Aspirin - 81 mg: ( 1 )
- d.** Celecoxib (Celebrex): ( 1 )
- e.** Ibuprofen (Advil, Motrin): ( 1 )
- f.** Indomethacin (Indocin): ( 1 )
- g.** Naproxen (Aleve, Naprosyn): ( 1 )
- h.** Rofecoxib (Vioxx): ( 1 )
- i.** Other, *(specify)*: ( 1 )

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

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

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

**61.**

*(If yes, check all that apply):*

- a.** Darvocet: ( 1 )
- b.** Esgic - Plus: ( 1 )
- c.** Fioricet: ( 1 )
- d.** Lorcet: ( 1 )
- e.** Lortab: ( 1 )
- f.** Norco: ( 1 )
- g.** Percocet: ( 1 )
- h.** Talacen: ( 1 )
- i.** Tylenol #3: ( 1 )
- j.** Tylenol #4: ( 1 )
- k.** Tylox: ( 1 )
- l.** Vicodin: ( 1 )
- m.** Wygesic: ( 1 )
- n.** Other, *(specify)*: ( 1 )

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

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

**62.**

*(If yes, check all that apply):*

- a.** Cimetidine (Tagamet): ( 1 )
- b.** Esomeprazole magnesium (Nexium): ( 1 )
- c.** Famotidine (Pepcid): ( 1 )
- d.** Lansoprazole (Prevacid): ( 1 )
- e.** Nizatidine (Axid): ( 1 )
- f.** Omeprazole (Prilosec): ( 1 )
- g.** Ranitidine (Zantac): ( 1 )
- h.** Ranitidine bismuth citrate (Tritec): ( 1 )
- i.** Antacids, *(specify)*: ( 1 )

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

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

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

**63.**

*(If yes, check all that apply):*

- a.** Clopidogrel (Plavix): ( 1 )
- b.** Dipyridamole: ( 1 )
- c.** Heparin: ( 1 )
- d.** Ticlopidine (Ticlid): ( 1 )
- e.** Warfarin (Coumadin): ( 1 )
- f.** Other, *(specify)*: ( 1 )

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

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

**64.**

*(If yes, check all that apply):*

- a.** Betamethasone sodium (Celestone): ( 1 )
- b.** Cortisol: ( 1 )
- c.** Cortisone: ( 1 )
- d.** Dexamethasone (Decadron): ( 1 )
- e.** Hydrocortisone (Hydrocortone): ( 1 )
- f.** Methylprednisolone (Solu-Medrol): ( 1 )
- g.** Prednisolone (Prelone): ( 1 )
- h.** Prednisone: ( 1 )
- i.** Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort): ( 1 )
- j.** Other, *(specify)*: ( 1 )
- 

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

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

**65.**

*(If yes, check all that apply):*

- a.** Amiodarone (Pacerone): ( 1 )
- b.** Amlodipine besylate (Norvasc): ( 1 )
- c.** Atenolol (Tenormin): ( 1 )
- d.** Benazepril (Lotensin): ( 1 )
- e.** Captopril (Capoten): ( 1 )
- f.** Clonidine (Catapres): ( 1 )
- g.** Digoxin (Lanoxin): ( 1 )
- h.** Diltiazem (Cardizem): ( 1 )
- i.** Doxazosin (Cardura): ( 1 )
- j.** Enalapril (Vasotec): ( 1 )
- k.** Felodipine (Plendil): ( 1 )
- l.** Furosemide (Lasix): ( 1 )
- m.** Hydrochlorothiazide (Esidrix, HydroDIURIL): ( 1 )
- n.** Hydrochlorothiazide + triamterene (Dyazide): ( 1 )
- o.** Lisinopril (Prinivil, Zestril): ( 1 )
- p.** Losartan potassium (Cozaar): ( 1 )
- q.** Losartan potassium with hydrochlorothiazide (Hyzaar): ( 1 )
- r.** Metoprolol (Lopressor): ( 1 )
- s.** Nifedipine (Adalat, Procardia): ( 1 )
- t.** Perhexiline maleate: ( 1 )
- u.** Propranolol (Inderal): ( 1 )
- v.** Quinapril (Accupril): ( 1 )
- w.** Terazosin (Hytrin): ( 1 )
- x.** Timolol maleate (Blocadren): ( 1 )
- y.** Valsartan (Diovan): ( 1 )
- z.** Verapamil (Calan): ( 1 )
- aa.** Other, *(specify)*: ( 1 )

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

---

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

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

**66.**

*(If yes, check all that apply):*

- a.** Conjugated estrogen (Premarin/Prempro):  ( 1 )
- b.** Diethylstilbestrol and methyltestosterone (Tylosterone):  ( 1 )
- c.** Esterified estrogen (Estratab, Menest):  ( 1 )
- d.** Estradiol (Estrace):  ( 1 )
- e.** Ethinyl estradiol (Estinyl):  ( 1 )
- f.** Fluoxymesterone (Android-F, Halotestin):  ( 1 )
- g.** Levonorgestrel (Norplant):  ( 1 )
- h.** Medroxyprogesterone (Cycrin, Provera):  ( 1 )
- i.** Megestrol (Megace):  ( 1 )
- j.** Methyltestosterone (Android):  ( 1 )
- k.** Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin):  ( 1 )
- l.** Norethindrone (Micronor):  ( 1 )
- m.** Norgestrel (Ovrette):  ( 1 )
- n.** Oral contraceptives:  ( 1 )
- o.** Oxandrolone (Oxandrin):  ( 1 )
- p.** Oxymetholone (Anadrol):  ( 1 )
- q.** Progesterone (Prometrium):  ( 1 )
- r.** Raloxifene (Evista):  ( 1 )
- s.** Tamoxifen (Nolvadex):  ( 1 )
- t.** Other, *(specify)*:  ( 1 )  
\_\_\_\_\_
- u.** Other, *(specify)*:  ( 1 )  
\_\_\_\_\_

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

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

**67.**

*(If yes, check all that apply):*

- a.** Beclomethasone dipropionate (Becloment, Vanciril):  ( 1 )
- b.** Budesonide (Pulmicort, Rhinocort):  ( 1 )
- c.** Fluticasone propionate (Flonase, Flovent):  ( 1 )
- d.** Loratadine (Claritin):  ( 1 )
- e.** Mometasone furoate (Nasonex):  ( 1 )
- f.** Triamcinolone acetonide (Azmacort, Nasacort):  ( 1 )
- g.** Other, *(specify)*:  ( 1 )  
\_\_\_\_\_
- h.** Other, *(specify)*:  ( 1 )  
\_\_\_\_\_

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

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

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

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

**70.**

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

- a.** Vitamin B (any type):  ( 1 )
- b.** Vitamin C:  ( 1 )
- c.** Vitamin D:  ( 1 )
- d.** Vitamin E:  ( 1 )
- e.** Other, *(specify)*:  ( 1 )  
\_\_\_\_\_

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

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

**71.**

*(If yes, check all that apply):*

- a.** Alpha-lipoic acid: ( 1 )
  - b.** Alpha-tocopherol: ( 1 )
  - c.** Beta-carotene: ( 1 )
  - d.** Betaine (Cystadane): ( 1 )
  - e.** Calcium (any form): ( 1 )
  - f.** Carnitine (any form): ( 1 )
  - g.** Chondroitin (any form): ( 1 )
  - h.** Choline + methionine + betaine + adenosine + pyridoxine (Epocler): ( 1 )
  - i.** Cod liver oil: ( 1 )
  - j.** Coenzyme Q: ( 1 )
  - k.** Dichloroacetate: ( 1 )
  - l.** Echinacea: ( 1 )
  - m.** Fish oil (any form): ( 1 )
  - n.** Flax seed oil: ( 1 )
  - o.** Garlic: ( 1 )
  - p.** Ginkgo biloba: ( 1 )
  - q.** Glucosamine (any form): ( 1 )
  - r.** Lecithin: ( 1 )
  - s.** Magnesium: ( 1 )
  - t.** Milk thistle: ( 1 )
  - u.** N-acetyl-cysteine: ( 1 )
  - v.** Potassium (any form): ( 1 )
  - w.** S-adenylmethionine (SAM-e): ( 1 )
  - x.** Saw palmetto: ( 1 )
  - y.** Selenium: ( 1 )
  - z.** St. John's Wort: ( 1 )
  - aa.** Taurine: ( 1 )
  - ab.** Zinc picolinate: ( 1 )
  - ac.** Other, *(specify)*: ( 1 )
- 
- ad.** Other, *(specify)*: ( 1 )
- 

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

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

**72.**

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

- a.** Demeclocycline (Declomycin): ( 1 )
  - b.** Divalproex (Depakote): ( 1 )
  - c.** Doxycycline (Monodox): ( 1 )
  - d.** Isotretinoin (Accutane): ( 1 )
  - e.** Levothyroxine (Levoxyl, Synthroid): ( 1 )
  - f.** Liothyronine (Cytomel): ( 1 )
  - g.** Methotrexate (Rheumatrex): ( 1 )
  - h.** Minocycline (Dynacin, Minocin): ( 1 )
  - i.** Oxytetracycline (Terramycin): ( 1 )
  - j.** Penicillamine (Cuprimine, Depen): ( 1 )
  - k.** Tetracycline (Achromycin): ( 1 )
  - l.** Trientine hydrochloride (Syprine): ( 1 )
  - m.** Ursodeoxycholic acid (Actigall, Urso, Ursodiol): ( 1 )
  - n.** Valproate sodium (Depacon): ( 1 )
  - o.** Valproic acid (Depakene): ( 1 )
  - p.** Other, *(specify)*: ( 1 )
- 
- q.** Other, *(specify)*: ( 1 )
- 
- r.** Other, *(specify)*: ( 1 )
-

**I. Administrative information**

72. Study Physician PIN: \_\_\_\_\_

73. Study Physician signature:  
\_\_\_\_\_

74. Clinical Coordinator PIN: \_\_\_\_\_

75. Clinical Coordinator signature:  
\_\_\_\_\_

76. Date form reviewed:):  
\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                  day                  mon                  year



- 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 )

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

( Yes ( \* 1 ) No ( 2 ) )

**21.** \_\_\_\_\_

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

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

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

**C. NAFLD history**

- 16.** Date patient was first diagnosed with fatty liver disease or NASH-related cirrhosis:
- \_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

- 21.** Will the patient have a biopsy during screening:
- ( Yes ( \* 1 ) No ( 2 ) )

- 17.** What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis (*check all that apply*)
- a.** Symptoms for liver disease: ( 1 )  
**b.** Result of being evaluated for another illness: ( 1 )  
**c.** During a routine or insurance physical examination: ( 1 )  
**d.** Blood donation: ( 1 )  
**e.** Other (*specify*): ( 1 )

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

- 22.** Has the patient had a liver imaging study in the past 6 months:
- ( Yes ( \* 1 ) No ( 2 ) )
- \*Complete the Liver Imaging Studies Report (IR) form.*

\_\_\_\_\_ specify

**D. Weight history**

- 18.** What procedures/tests supported this first diagnosis (*check all that apply*)
- a.** Liver biopsy: ( 1 )  
**b.** Imaging studies (*Ultrasound, CT, MRI*): ( 1 )  
**c.** Elevated aminotransferases: ( 1 )  
**d.** Other (*specify*): ( 1 )

- 23.** What was the patient's birthweight:
- \_\_\_\_\_ lbs \_\_\_\_\_ oz

\_\_\_\_\_ specify

- 24.** Review flashcard 11. Which (picture) best describes your weight pattern over the past 5 years (*check only one*):
- Up and down, up and down ( 1 )  
 Up gradually ( 2 )  
 Up sharply (*gained a lot in a brief interval*) ( 3 )  
 Down gradually ( 4 )  
 Down sharply (*lost a lot in a brief interval*) ( 5 )  
 No or minimal change ( 6 )



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

26. What is the most the patient has ever  
weighed:  
\_\_\_\_\_ lbs

27. At what age did the patient weigh the  
most:  
\_\_\_\_\_ age in years

28. Is the patient age 18 or older:  
 Yes ( 1 )  No ( 2 )  
31.

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

30. At what age did the patient weigh the  
least since age 18:  
\_\_\_\_\_ age in years

31. Does the patient weigh more than he/she  
did one year ago:  
 Yes ( 1 )  No ( 2 )  
33.

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

33. Does the patient weigh less than he/she  
did one year ago:  
 Yes ( 1 )  No ( 2 )  
35.

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

35. Did the patient try to lose or gain weight:  
 Yes ( 1 )  No ( 2 )  
37.

36. Which did the patient try to do (check only one):  
Gain weight ( 1 )  
Lose weight ( 2 )

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

37. Is the patient age 12 or older:  
 Yes ( 1 )  No ( 2 )  
43.

38. Have you ever smoked tobacco cigarettes:  
Never ( 1 )  
In the past but not anymore ( 2 )  
Currently smokes cigarettes ( 3 )  
43.

39. Did you smoke cigarettes regularly ("No" means  
less than 20 packs of cigarettes in a lifetime or less  
than 1 cigarette a day for one year):  
 Yes ( 1 )  No ( 2 )  
43.

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

41. How old were you when you (last)  
stopped smoking cigarettes (code as "n" if the pa-  
tient didn't stop smoking):  
\_\_\_\_\_ years

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

**F. Menstrual history**

43. Is the patient female:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 49.

44. Has menarche occurred:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 49.

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

\_\_\_\_\_  
 age in years

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

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

47. Is patient post-menopausal:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 49.

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

\_\_\_\_\_  
 age in years

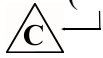
**G. Medical history** ( $\triangle C$  means Caution; condition is exclusionary if study physician agrees with diagnosis)

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

- a. Diabetes type 1: ( 1 )
- b. Diabetes type 2: ( 1 )
- c. Gestational diabetes (diabetes of pregnancy): ( 1 )
- d. Hepatitis B:  $\triangle C$  ( 1 )
- e. Hepatitis C:  $\triangle C$  ( 1 )

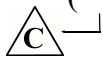
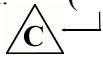
- f. Autoimmune hepatitis: ( 1 )
- g. Autoimmune cholestatic liver disorder (PBC or PSC):  $\triangle C$  ( 1 )
- h. Wilson's disease:  $\triangle C$  ( 1 )
- i. Alpha-1-antitrypsin (A1AT) deficiency:  $\triangle C$  ( 1 )
- j. Glycogen storage disease:  $\triangle C$  ( 1 )
- k. Iron overload:  $\triangle C$  ( 1 )
- l. Polycystic liver disease: ( 1 )
- m. Drug induced liver disease: ( 1 )
- n. Gilbert's syndrome: ( 1 )
- o. Esophageal or gastric varices on endoscopy: ( 1 )
- p. Bleeding from varices: ( 1 )
- q. Other gastrointestinal bleeding: ( 1 )
- r. Ascites: ( 1 )
- s. Edema: ( 1 )
- t. Hepatic encephalopathy: ( 1 )
- u. Portal hypertension: ( 1 )
- v. Hepatorenal syndrome: ( 1 )
- w. Hepatopulmonary syndrome: ( 1 )
- x. Short bowel syndrome:  $\triangle C$  ( 1 )
- y. Hemophilia (bleeding disorder):  $\triangle C$  ( 1 )
- z. HIV positive:  $\triangle C$  ( 1 )
- aa. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: ( 1 )
- ab. Endocrine disease (hormonal abnormality): ( 1 )
- ac. Hepatocellular carcinoma:  $\triangle C$  ( 1 )
- ad. Other malignancy (cancer): ( 1 )
- ae. Peripheral neuropathy: ( 1 )

- af. Seizure disorder or epilepsy: (  )
- ag. Drug allergies: (  )
- ah. Hypothyroidism: (  )
- ai. Hypertension: (  )
- aj. Cerebrovascular disease: (  )
- ak. Dysbetalipoproteinemia: (  )
- al. Chronic cholestasis: (  )
- am. Hyperlipidemia (*high cholesterol, high triglycerides*): (  )
- an. Pancreatitis: (  )
- ao. Cholelithiasis: (  )
- ap. Coronary artery disease: (  )
- aq. Elevated uric acid such as gout: (  )
- ar. Kidney disease: (  )
- as. Polycystic ovary syndrome: (  )
- at. Sleep apnea (*not breathing during sleep*): (  )
- au. Dermatologic disorders: (  )
- av. Myopathy: (  )
- aw. Myositis: (  )
- ax. Major depression: (  )
- ay. Schizophrenia: (  )
- az. Bipolar disorder: (  )
- ba. Obsessive compulsive disorder: (  )
- bb. Severe anxiety or personality disorder: (  )
- bc. None of the above: (  )



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

- a. Stapling or banding of the stomach: (  )
  - b. Jejunioileal (*or other intestinal*) bypass prior to the diagnosis of NAFLD: (  )
  - c. Biliopancreatic diversion: (  )
  - d. Other GI or bariatric surgery (*specify*): (  )
- 
- e. None of the above: (  )



51. Organ, limb, or bone marrow transplant

a. Has the patient ever received a liver transplant:

(  ) Yes (  ) No

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

(  ) Yes (  ) No

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

(  ) Yes (  ) No



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

(  ) Yes (  ) No

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

(  ) Yes (  ) No

**H. Medication use**

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

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

**56.**

*(If yes, check all that apply):*

- a.** Acarbose (Precose): ( 1 )
- b.** Acetohexamide (Dymelor): ( 1 )
- c.** Chlorpropamide (Diabinese): ( 1 )
- d.** Glimepiride (Amaryl): ( 1 )
- e.** Glipizide (Glucotrol, Glucotrol XL): ( 1 )
- f.** Glyburide (Micronase, DiaBeta, Glynase): ( 1 )
- g.** Insulin: ( 1 )
- h.** Metformin (Glucophage, Glucophage XR): ( 1 )
- i.** Miglitol (Glycet): ( 1 )
- j.** Nateglinide (Starlix): ( 1 )
- k.** Pioglitazone (Actos): ( 1 )
- l.** Repaglinide (Prandin): ( 1 )
- m.** Rosiglitazone (Avandia): ( 1 )
- n.** Tolazamide (Tolinase): ( 1 )
- o.** Tolbutamide (Orinase): ( 1 )
- p.** Other, *(specify)*: ( 1 )

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

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

**57.**

*(If yes, check all that apply):*

- a.** Chlordiazepoxide (Librium): ( 1 )
- b.** Clorazepate dipotassium (Tranxene): ( 1 )
- c.** Diazepam (Valium): ( 1 )
- d.** Disulfiram (Antabuse): ( 1 )
- e.** Hydroxyzine pamoate (Vistaril): ( 1 )
- f.** Naltrexone hydrochloride (Revia): ( 1 )
- g.** Other, *(specify)*: ( 1 )

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

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

**58.**

*(If yes, check all that apply):*

- a.** Atorvastatin (Lipitor): ( 1 )
- b.** Colestipol hydrochloride (Colestid): ( 1 )
- c.** Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): ( 1 )
- d.** Gemfibrozil (Gen-Fibro, Lopid): ( 1 )
- e.** Fenofibrate (Tricor): ( 1 )
- f.** Fluvastatin sodium (Lescol): ( 1 )
- g.** Lovastatin (Mevacor): ( 1 )
- h.** Nicotinic acid (Niaspan): ( 1 )
- i.** Pravastatin sodium (Pravachol): ( 1 )
- j.** Rosuvastatin (Crestor): ( 1 )
- k.** Simvastatin (Zocor): ( 1 )
- l.** Other, *(specify)*: ( 1 )

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

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

**59.**

*(If yes, check all that apply):*

- a.** Dexfenfluramine hydrochloride (Redux): ( 1 )
- b.** Fenfluramine hydrochloride (Pondimin): ( 1 )
- c.** Methamphetamine hydrochloride (Desoxyn, Gradumet): ( 1 )
- d.** Orlistat (Xenical): ( 1 )
- e.** Phendimetrazine tartrate (Adipost, Bontril): ( 1 )
- f.** Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine): ( 1 )
- g.** Sibutramine hydrochloride monohydrate (Meridia): ( 1 )
- h.** Other, *(specify)*: ( 1 )

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

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

**60.**

*(If yes, check all that apply):*

- a.** Acetaminophen (Tylenol): ( 1 )
- b.** Aspirin - 325 mg: ( 1 )
- c.** Aspirin - 81 mg: ( 1 )
- d.** Celecoxib (Celebrex): ( 1 )
- e.** Ibuprofen (Advil, Motrin): ( 1 )
- f.** Indomethacin (Indocin): ( 1 )
- g.** Naproxen (Aleve, Naprosyn): ( 1 )
- h.** Rofecoxib (Vioxx): ( 1 )
- i.** Other, *(specify)*: ( 1 )

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

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

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

**61.**

*(If yes, check all that apply):*

- a.** Darvocet: ( 1 )
- b.** Esgic - Plus: ( 1 )
- c.** Fioricet: ( 1 )
- d.** Lorcet: ( 1 )
- e.** Lortab: ( 1 )
- f.** Norco: ( 1 )
- g.** Percocet: ( 1 )
- h.** Talacen: ( 1 )
- i.** Tylenol #3: ( 1 )
- j.** Tylenol #4: ( 1 )
- k.** Tylox: ( 1 )
- l.** Vicodin: ( 1 )
- m.** Wygesic: ( 1 )
- n.** Other, *(specify)*: ( 1 )

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

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

**62.**

*(If yes, check all that apply):*

- a.** Cimetidine (Tagamet): ( 1 )
- b.** Esomeprazole magnesium (Nexium): ( 1 )
- c.** Famotidine (Pepcid): ( 1 )
- d.** Lansoprazole (Prevacid): ( 1 )
- e.** Nizatidine (Axid): ( 1 )
- f.** Omeprazole (Prilosec): ( 1 )
- g.** Ranitidine (Zantac): ( 1 )
- h.** Ranitidine bismuth citrate (Tritec): ( 1 )
- i.** Antacids, *(specify)*: ( 1 )

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

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

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

**63.**

*(If yes, check all that apply):*

- a.** Clopidogrel (Plavix): ( 1 )
- b.** Dipyridamole: ( 1 )
- c.** Heparin: ( 1 )
- d.** Ticlopidine (Ticlid): ( 1 )
- e.** Warfarin (Coumadin): ( 1 )
- f.** Other, *(specify)*: ( 1 )

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

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

**64.**

*(If yes, check all that apply):*

- a.** Betamethasone sodium (Celestone):      ( 1 )
  - b.** Cortisol:      ( 1 )
  - c.** Cortisone:      ( 1 )
  - d.** Dexamethasone (Decadron):      ( 1 )
  - e.** Hydrocortisone (Hydrocortone):      ( 1 )
  - f.** Methylprednisolone (Solu-Medrol):      ( 1 )
  - g.** Prednisolone (Prelone):      ( 1 )
  - h.** Prednisone:      ( 1 )
  - i.** Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort):      ( 1 )
  - j.** Other, *(specify)*:      ( 1 )
- 

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

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

**65.**

*(If yes, check all that apply):*

- a.** Amiodarone (Pacerone):      ( 1 )
- b.** Amlodipine besylate (Norvasc):      ( 1 )
- c.** Atenolol (Tenormin):      ( 1 )
- d.** Benazepril (Lotensin):      ( 1 )
- e.** Captopril (Capoten):      ( 1 )
- f.** Clonidine (Catapres):      ( 1 )
- g.** Digoxin (Lanoxin):      ( 1 )
- h.** Diltiazem (Cardizem):      ( 1 )
- i.** Doxazosin (Cardura):      ( 1 )
- j.** Enalapril (Vasotec):      ( 1 )
- k.** Felodipine (Plendil):      ( 1 )
- l.** Furosemide (Lasix):      ( 1 )
- m.** Hydrochlorothiazide (Esidrix, HydroDIURIL):      ( 1 )
- n.** Hydrochlorothiazide + triamterene (Dyazide):      ( 1 )
- o.** Lisinopril (Prinivil, Zestril):      ( 1 )
- p.** Losartan potassium (Cozaar):      ( 1 )
- q.** Losartan potassium with hydrochlorothiazide (Hyzaar):      ( 1 )
- r.** Metoprolol (Lopressor):      ( 1 )
- s.** Nifedipine (Adalat, Procardia):      ( 1 )
- t.** Perhexiline maleate:      ( 1 )
- u.** Propranolol (Inderal):      ( 1 )
- v.** Quinapril (Accupril):      ( 1 )
- w.** Terazosin (Hytrin):      ( 1 )
- x.** Timolol maleate (Blocadren):      ( 1 )
- y.** Valsartan (Diovan):      ( 1 )
- z.** Verapamil (Calan):      ( 1 )
- aa.** Other, *(specify)*:      ( 1 )

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

---

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

Yes ( 1 )      No ( 2 )  
**66.**

*(If yes, check all that apply):*

- a.** Conjugated estrogen (Premarin/Prempro): ( 1 )
- b.** Diethylstilbestrol and methyltestosterone (Tylosterone): ( 1 )
- c.** Esterified estrogen (Estratab, Menest): ( 1 )
- d.** Estradiol (Estrace): ( 1 )
- e.** Ethinyl estradiol (Estinyl): ( 1 )
- f.** Fluoxymesterone (Android-F, Halotestin): ( 1 )
- g.** Levonorgestrel (Norplant): ( 1 )
- h.** Medroxyprogesterone (Cycrin, Provera): ( 1 )
- i.** Megestrol (Megace): ( 1 )
- j.** Methyltestosterone (Android): ( 1 )
- k.** Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin): ( 1 )
- l.** Norethindrone (Micronor): ( 1 )
- m.** Norgestrel (Ovrette): ( 1 )
- n.** Oral contraceptives: ( 1 )
- o.** Oxandrolone (Oxandrin): ( 1 )
- p.** Oxymetholone (Anadrol): ( 1 )
- q.** Progesterone (Prometrium): ( 1 )
- r.** Raloxifene (Evista): ( 1 )
- s.** Tamoxifen (Nolvadex): ( 1 )
- t.** Other, *(specify)*: ( 1 )  
\_\_\_\_\_
- u.** Other, *(specify)*: ( 1 )  
\_\_\_\_\_

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

Yes ( 1 )      No ( 2 )  
**67.**

*(If yes, check all that apply):*

- a.** Beclomethasone dipropionate (Becloment, Vanciril): ( 1 )
- b.** Budesonide (Pulmicort, Rhinocort): ( 1 )
- c.** Fluticasone propionate (Flonase, Flovent): ( 1 )
- d.** Loratadine (Claritin): ( 1 )
- e.** Mometasone furoate (Nasonex): ( 1 )
- f.** Triamcinolone acetonide (Azmecort, Nasacort): ( 1 )
- g.** Other, *(specify)*: ( 1 )  
\_\_\_\_\_
- h.** Other, *(specify)*: ( 1 )  
\_\_\_\_\_

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

Yes ( 1 )      No ( 2 )

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

Yes ( 1 )      No ( 2 )  
**70.**

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

- a.** Vitamin B (any type): ( 1 )
- b.** Vitamin C: ( 1 )
- c.** Vitamin D: ( 1 )
- d.** Vitamin E: ( 1 )
- e.** Other, *(specify)*: ( 1 )  
\_\_\_\_\_

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

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

**71.**

*(If yes, check all that apply):*

- a.** Alpha-lipoic acid: ( 1 )
  - b.** Alpha-tocopherol: ( 1 )
  - c.** Beta-carotene: ( 1 )
  - d.** Betaine (Cystadane): ( 1 )
  - e.** Calcium (any form): ( 1 )
  - f.** Carnitine (any form): ( 1 )
  - g.** Chondroitin (any form): ( 1 )
  - h.** Choline + methionine + betaine + adenosine + pyridoxine (Epocler): ( 1 )
  - i.** Cod liver oil: ( 1 )
  - j.** Coenzyme Q: ( 1 )
  - k.** Dichloroacetate: ( 1 )
  - l.** Echinacea: ( 1 )
  - m.** Fish oil (any form): ( 1 )
  - n.** Flax seed oil: ( 1 )
  - o.** Garlic: ( 1 )
  - p.** Ginkgo biloba: ( 1 )
  - q.** Glucosamine (any form): ( 1 )
  - r.** Lecithin: ( 1 )
  - s.** Magnesium: ( 1 )
  - t.** Milk thistle: ( 1 )
  - u.** N-acetyl-cysteine: ( 1 )
  - v.** Potassium (any form): ( 1 )
  - w.** S-adenylmethionine (SAM-e): ( 1 )
  - x.** Saw palmetto: ( 1 )
  - y.** Selenium: ( 1 )
  - z.** St. John's Wort: ( 1 )
  - aa.** Taurine: ( 1 )
  - ab.** Zinc picolinate: ( 1 )
  - ac.** Other, *(specify)*: ( 1 )
- 
- ad.** Other, *(specify)*: ( 1 )
- 

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

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

**72.**

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

- a.** Demeclocycline (Declomycin): ( 1 )
  - b.** Divalproex (Depakote): ( 1 )
  - c.** Doxycycline (Monodox): ( 1 )
  - d.** Isotretinoin (Accutane): ( 1 )
  - e.** Levothyroxine (Levoxyl, Synthroid): ( 1 )
  - f.** Liothyronine (Cytomel): ( 1 )
  - g.** Methotrexate (Rheumatrex): ( 1 )
  - h.** Minocycline (Dynacin, Minocin): ( 1 )
  - i.** Oxytetracycline (Terramycin): ( 1 )
  - j.** Penicillamine (Cuprimine, Depen): ( 1 )
  - k.** Tetracycline (Achromycin): ( 1 )
  - l.** Trientine hydrochloride (Syprine): ( 1 )
  - m.** Ursodeoxycholic acid (Actigall, Urso, Ursodiol): ( 1 )
  - n.** Valproate sodium (Depacon): ( 1 )
  - o.** Valproic acid (Depakene): ( 1 )
  - p.** Other, *(specify)*: ( 1 )
- 
- q.** Other, *(specify)*: ( 1 )
- 
- r.** Other, *(specify)*: ( 1 )
-



**I. Administrative information**

72. Study Physician PIN: \_\_\_\_\_

73. Study Physician signature:  
\_\_\_\_\_

74. Clinical Coordinator PIN: \_\_\_\_\_

75. Clinical Coordinator signature:  
\_\_\_\_\_

76. Date form reviewed:  
\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day mon year

## NAFLD Database 2

## BQ – Beverage Questionnaire (BEVQ-15)

**Purpose:** To obtain the patient's beverage intake.

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

**By whom:** Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.

**Respondent:** Patient or completed by patient with parental assistance.

**Instructions:** The Clinical Coordinator should complete section A and attach a label to page 2 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to page 2 and the Clinical Coordinator should complete section C.

## A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of visit :

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                   day                  mon                  year

5. Visit code:          t   \_\_\_\_\_

6. Form & revision:                 b     q     1  

7. Study:                NAFLD Database 2   6  

## C. Administrative information

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

24. Clinical Coordinator PIN: \_\_\_\_\_

25. Clinical Coordinator signature:  
 \_\_\_\_\_

26. Date form reviewed:  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                   day                  mon                  year

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

- 1) Indicate how often you drank the following beverages, for example, if you drank 5 glasses of water per week, circle response “3” under the column labeled “4-6 time per week”.
- 2) Indicate the approximate amount of beverage you drank each time, for example, you drank 1 cup of water each time, circle response “2” under the column labeled “8 fl oz (1 cup)” under “how much each time.”
- 3) Do not count beverages used in cooking or other preparations, such as milk in cereal.
- 4) Count milk added to tea and coffee in the *tea/coffee with cream beverage category* **NOT** in the milk categories.

Affix label here

Patient ID: \_\_\_\_\_

Patient code: \_\_\_\_\_

Visit code: \_\_\_\_\_

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

## NAFLD Database 2 CG - Genetic Consent and Blood Collection Documentation

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

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

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

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

### A. Center, patient and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date form completed:  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

5. Visit code: \_\_\_\_\_

6. Form & revision: c g 1

7. Study: NAFLD Database 2 6

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

Yes ( 1 ) No ( 2 )

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

Yes ( 1 ) No ( 2 )

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

Yes ( 1 ) No ( 2 )

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

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

Yes ( 1 ) No ( 2 )

10.

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

a. Database ( 1 )

b. PIVENS ( 1 )

c. TONIC ( 1 )

d. Other, (specify): ( 1 )

\_\_\_\_\_ specify

20.

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

Yes (  )      No (  )  
**20.** \_\_\_\_\_

**C. Specimen for Genetics Repository**

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

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

Yes (  )  
**16.** \_\_\_\_\_  
 No, (*specify*): (  )

\_\_\_\_\_ specify  
**20.** \_\_\_\_\_

**16.** Date and time of blood draw

**a. Date:**  
 \_\_\_\_\_  
 day                      mon                      year

**b. Time:**  
 \_\_\_\_\_ : \_\_\_\_\_ (  ) (  )  
 hour                      minute                      am                      pm

**17.** Number of 10 mL EDTA tubes: \_\_\_\_\_

**18.** Form copy of tube labels:

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

**19.** Phlebotomist:

\_\_\_\_\_ print name

**D. Administrative information**

**20.** Study Physician PIN: \_\_\_\_\_

**21.** Study Physician signature:  
 \_\_\_\_\_

**22.** Clinical Coordinator PIN: \_\_\_\_\_

**23.** Clinical Coordinator signature:  
 \_\_\_\_\_

**24.** Date form reviewed:  
 \_\_\_\_\_  
 day                      mon                      year

## NAFLD Database 2 CG - Genetic Consent and Blood Collection Documentation

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

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

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

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

### A. Center, patient and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date form completed:  
 \_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

5. Visit code: \_\_\_\_\_

6. Form & revision: c g 2

7. Study: NAFLD Database 2 6

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

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

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

10.

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

a. Database ( 1 )

b. PIVENS ( 1 )

c. TONIC ( 1 )

d. Other, (specify): ( 1 )

\_\_\_\_\_ specify

20.

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

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

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

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

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

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

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



### Central Histology Review

**Purpose:** Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.

**When:** Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.

**By whom:** Data Coordinating Center staff.

**Instructions:** Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

**A. Clinic, patient and visit identification**

- \_\_\_ \_\_\_ \_\_\_ 1. Center ID
- \_\_\_ \_\_\_ \_\_\_ 2. Patient ID
- \_\_\_ \_\_\_ \_\_\_ 3. Patient code
- \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ 4. Date of central reading
- \_\_\_ \_\_\_ \_\_\_ 5. Visit code
- c  r  2   6. Form and revision
- \_\_\_ 7. Study: **6**=Database 2; **7**=FLINT
- \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ 8. Date of biopsy

**B. Slide sequence number**

- \_\_\_ \_\_\_ 9. Sequence number for
  - ... a. H & E stained slide
  - \_\_\_ \_\_\_ ... b. Masson’s trichrome stained slide
  - \_\_\_ \_\_\_ ... c. Iron stained slide

**C. Adequacy of biopsy**

- \_\_\_ \_\_\_ 10. Biopsy length (mm)
- \_\_\_ 11. Tissue adequate: **0**=No → Request original slides from submitting clinic; **1**=Yes
- \_\_\_\_\_ 12. Followup with clinic (*Specify*):

**D. Histology**

**H & E stain**

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

- \_\_\_ \_\_\_ ... a. Grade: **0**<5%; **1**=5-33%; **2**=34-66%; **3**>66%
- \_\_\_ \_\_\_ ... b. Location: **0**=Zone 3 (*central*); **1**=Zone 1 (*periportal*); **2**=Azonal; **3**=Panacinar
- \_\_\_ \_\_\_ ... c. Type of macrovesicular steatosis: **0**=Predominantly large droplet; **1**=Mixed large and small droplet; **2**=Predominantly small droplet
- \_\_\_ \_\_\_ ... d. Microvesicular steatosis, contiguous patches: **0**=Absent; **1**=Present



## 14. Inflammation

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

## 15. Liver cell injury

- ... a. Ballooning: **0=None → GOTO Item 15d; 1=Few; 2=Many**
- ... b. Severe ballooning present: **0=No; 1=Yes**
- ... c. Classical balloon cells present: **0=No; 1=Yes**
- ... d. Acidophil bodies: **0=Rare/absent; 1=Many**
- ... e. Pigmented macrophages (*Kupffer cells*): **0=Rare/absent; 1=Many**
- ... f. Megamitochondria: **0=Rare/absent; 1=Many**

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

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

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

## 19. Masson's trichrome stain

- ... a. Fibrosis stage: **0=None → GOTO Item 20; 1a=Mild, zone 3 perisinusoidal (requires trichrome); 1b=Moderate, zone 3, perisinusoidal (does not require trichrome); 1c=Portal/periportal only; 2=Zone 3 and periportal, any combination; 3=Bridging; 4=Cirrhosis**
- ... b. Perisinusoidal fibrosis grade: **0=No perisinusoidal fibrosis present; 1=Perisinusoidal fibrosis present that requires a Masson stain to identify; 2=Perisinusoidal fibrosis present that is visible on the H&E stain**
- ... c. Predominant location of fibrosis: **0=More predominance around or between portal areas; 1=No portal or central predominance; 2=More predominance around/between central veins**

## 20. Iron stain

- ... a. Hepatocellular iron grade: **0=Absent or barely discernible, 40x → GOTO item 20c; 1=Barely discernible granules, 20x; 2=Discrete granules resolved, 10x; 3=Discrete granules resolved, 4x; 4=Masses visible by naked eye**
- ... b. Hepatocellular iron distribution: **0=Periportal; 1=Periportal and midzonal; 2=Panacinar; 3=Zone 3 or azonal**
- ... c. Nonhepatocellular iron grade: **0=None → GOTO item 21; 1=Mild; 2=More than mild**
- ... d. Nonhepatocellular iron distribution: **0=Large vessel endothelium only; 1=Portal/fibrosis bands only, but more than just in large vessel endothelium; 2=Intraparenchymal only; 3=Both portal and intraparenchymal**

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

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

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

24. Features suggestive of steatohepatitis etiology for cryptogenic cirrhosis:

- ... a. Mallory-Denk bodies (*rule out cholate stasis*): **0=Absent; 1=Present**
- ... b. Perisinusoidal fibrosis away from septa: **0=Absent; 1=Present**
- ... c. Hepatocyte ballooning: **0=Absent; 1=Present**
- ... d. Megamitochondria: **0=Absent; 1=Present**
- ... e. Other notable findings: **0=Absent; 1=Present; Specify: \_\_\_\_\_**

25. Other comments: \_\_\_\_\_

### Central Histology Review

**Purpose:** Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.

**When:** Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.

**By whom:** Data Coordinating Center staff.

**Instructions:** Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

**A. Clinic, patient and visit identification**

- \_\_\_\_\_ 1. Center ID
- \_\_\_\_\_ 2. Patient ID
- \_\_\_\_\_ 3. Patient code
- \_\_\_\_ / \_\_\_\_ / \_\_\_\_ 4. Date of central reading
- \_\_\_\_\_ 5. Visit code
- c  r  3   6. Form and revision
- \_\_\_\_\_ 7. Study: **6**=Database 2; **9**=STOP-NAFLD
- \_\_\_\_ / \_\_\_\_ / \_\_\_\_ 8. Date of biopsy

**B. Slide sequence number**

- \_\_\_\_\_ 9. Sequence number for
  - ... a. H & E stained slide
  - \_\_\_\_\_ ... b. Masson’s trichrome stained slide
  - \_\_\_\_\_ ... c. Iron stained slide

**C. Adequacy of biopsy**

- \_\_\_\_\_ 10. Biopsy length (mm)
- \_\_\_\_\_ 11. Tissue adequate: **0**=No → Request original slides from submitting clinic; **1**=Yes
- \_\_\_\_\_ 12. Followup with clinic (*Specify*):

## D. Histology

\_\_\_\_\_ Patient ID

### H & E stain

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

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

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

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

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

14. Inflammation

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

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

15. Liver cell injury

\_\_\_\_\_ ... a. Ballooning: **0**=None → **GOTO Item 15d**; **1**=Few; **2**=Many

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

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

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

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

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

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

### 19. Masson's trichrome stain

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

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

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

### 20. Iron stain

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

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

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

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

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

25. Other comments: \_\_\_\_\_

### Central Histology Review

**Purpose:** Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.

**When:** Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.

**By whom:** Data Coordinating Center staff.

**Instructions:** Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

**A. Clinic, patient and visit identification**

- \_\_\_ \_\_\_ \_\_\_ 1. Center ID
- \_\_\_ \_\_\_ \_\_\_ 2. Patient ID
- \_\_\_ \_\_\_ \_\_\_ 3. Patient code
- \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ 4. Date of central reading
- \_\_\_ \_\_\_ \_\_\_ 5. Visit code
- c  r  4   6. Form and revision
- \_\_\_ 7. Study: **10**=VEDS; **11**=Database 3
- \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ 8. Date of biopsy

**B. Slide sequence number**

- \_\_\_ \_\_\_ 9. Sequence number for
- ... a. H & E stained slide
- \_\_\_ \_\_\_ ... b. Masson’s trichrome stained slide
- \_\_\_ \_\_\_ ... c. Iron stained slide

**C. Adequacy of biopsy**

- \_\_\_ \_\_\_ 10. Biopsy length (mm)
- \_\_\_ 11. Tissue adequate: **0**=No → Request original slides from submitting clinic; **1**=Yes
- \_\_\_\_\_ 12. Followup with clinic (*Specify*):

## D. Histology

\_\_\_\_\_ Patient ID

### H & E stain

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

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

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

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

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

14. Inflammation

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

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

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

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

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

15. Liver cell injury

\_\_\_\_\_ ... a. Ballooning: **0**=None → **GOTO Item 15d**; **1**=Few; **2**=Many

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

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

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

### 17. Masson's trichrome stain

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

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

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

### 18. Iron stain

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

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

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

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

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

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

\_\_\_\_\_ 21. Other comments: \_\_\_\_\_



**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
No  
( 1 )
( 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*)

- |  |   |
|--|---|
| <p>a. Diabetes type 1: ( 1 )</p> <p>b. Diabetes type 2: ( 1 )</p> <p>c. Gestational diabetes (<i>diabetes of pregnancy</i>): ( 1 )</p> <p>d. Hepatitis B: ( 1 )</p> <p>e. Hepatitis C: ( 1 )</p> <p>f. Autoimmune hepatitis: ( 1 )</p> <p>g. Autoimmune cholestatic liver disorder (PBC or PSC): ( 1 )</p> <p>h. Wilson’s disease: ( 1 )</p> <p>i. Alpha-1-antitrypsin (A1AT) deficiency: ( 1 )</p> <p>j. Iron overload: ( 1 )</p> <p>k. Drug induced liver disease: ( 1 )</p> <p>l. Gilbert’s syndrome: ( 1 )</p> <p>m. Esophageal or gastric varices on endoscopy: ( 1 )</p> <p>n. Bleeding from varices: ( 1 )</p> <p>o. Other gastrointestinal bleeding: ( 1 )</p> <p>p. Ascites: ( 1 )</p> <p>q. Edema: ( 1 )</p> | <p>r. Hepatic encephalopathy: ( 1 )</p> <p>s. Portal hypertension: ( 1 )</p> <p>t. Hepatorenal syndrome: ( 1 )</p> <p>u. Hepatopulmonary syndrome: ( 1 )</p> <p>v. Short bowel syndrome: ( 1 )</p> <p>w. Hemophilia (<i>bleeding disorder</i>): ( 1 )</p> <p>x. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: ( 1 )</p> <p>y. Endocrine disease (<i>hormonal abnormality</i>): ( 1 )</p> <p>z. Hepatocellular carcinoma: ( 1 )</p> <p>aa. Other malignancy (<i>cancer</i>): ( 1 )</p> <p>ab. Peripheral neuropathy: ( 1 )</p> <p>ac. Seizure disorder or epilepsy: ( 1 )</p> <p>ad. Drug allergies: ( 1 )</p> <p>ae. Hypothyroidism: ( 1 )</p> <p>af. Hypertension: ( 1 )</p> <p>ag. Cerebrovascular disease: ( 1 )</p> <p>ah. Dysbetalipoproteinemia: ( 1 )</p> <p>ai. Hyperlipidemia (<i>high cholesterol, high triglycerides</i>): ( 1 )</p> <p>aj. Pancreatitis: ( 1 )</p> <p>ak. Cholelithiasis: ( 1 )</p> <p>al. Coronary artery disease: ( 1 )</p> <p>am. Elevated uric acid such as gout: ( 1 )</p> <p>an. Kidney disease: ( 1 )</p> <p>ao. Polycystic ovary syndrome: ( 1 )</p> <p>ap. Sleep apnea (<i>not breathing during sleep</i>): ( 1 )</p> <p>aq. Dermatologic disorders: ( 1 )</p> <p>ar. Myopathy: ( 1 )</p> <p>as. Myositis: ( 1 )</p> <p>at. Major depression: ( 1 )</p> <p>au. Schizophrenia: ( 1 )</p> <p>av. Bipolar disorder: ( 1 )</p> <p>aw. Obsessive compulsive disorder: ( 1 )</p> <p>ax. Severe anxiety or personality disorder: ( 1 )</p> <p>ay. None of the above: ( 1 )</p> |
|--|---|

- 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. Jejunioleal (*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 ) ( No )  
( 1 ) ( 2 )

- 22.** Since the last visit, has the patient received total parenteral nutrition (TPN):
- ( Yes ) ( No )  
( 1 ) ( 2 )

- 23.** Is the patient currently undergoing evaluation for bariatric surgery:
- ( Yes ) ( No )  
( 1 ) ( 2 )

- 24.** Since the last visit, has the patient been hospitalized:
- ( Yes ) ( No )  
( 1 ) ( 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 ) ( No )  
( 1 ) ( 2 )
- 26.**

*If Yes, specify:*

\_\_\_\_\_

specify

**G. Medication use**

- 26.** Since the last visit, has the patient used any antidiabetic medications (*If yes, check all that apply*)
- ( Yes ) ( No )  
( 1 ) ( 2 )
- 27.**
- a. Acarbose (Precose): ( 1 )
  - b. Acetohexamide (Dymelor): ( 1 )
  - c. Chlorpropamide (Diabinese): ( 1 )
  - d. Glimepiride (Amaryl): ( 1 )
  - e. Glipizide (Glucotrol, Glucotrol XL): ( 1 )
  - f. Glyburide (Micronase, DiaBeta, Glynase): ( 1 )
  - g. Insulin: ( 1 )
  - h. Metformin (Glucophage, Glucophage XR): ( 1 )
  - i. Miglitol (Glycet): ( 1 )
  - j. Nateglinide (Starlix): ( 1 )
  - k. Pioglitazone (Actos): ( 1 )
  - l. Repaglinide (Prandin): ( 1 )
  - m. Rosiglitazone (Avandia): ( 1 )
  - n. Tolazamide (Tolinase): ( 1 )
  - o. Tolbutamide (Orinase): ( 1 )
  - p. Other, (*specify*): ( 1 )

- 27.** Since the last visit, has the patient taken any alcohol abuse (dependence or withdrawal) medications:
- ( Yes ) ( No )  
( 1 ) ( 2 )



28. Since the last visit, has the patient taken any antihyperlipidemic medications (If yes, check all that apply)

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

**29.**

- a. Atorvastatin (Lipitor): ( 1 )
- b. Colestipol hydrochloride (Colestid): ( 1 )
- c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): ( 1 )
- d. Gemfibrozil (Gen-Fibro, Lopid): ( 1 )
- e. Fenofibrate (Tricor): ( 1 )
- f. Fluvastatin sodium (Lescol): ( 1 )
- g. Lovastatin (Mevacor): ( 1 )
- h. Nicotinic acid (Niaspan): ( 1 )
- i. Pravastatin sodium (Pravachol): ( 1 )
- j. Rosuvastatin (Crestor): ( 1 )
- k. Simvastatin (Zocor): ( 1 )
- l. Other, (specify): ( 1 )

29. Since the last visit, has the patient taken any antiobesity medications:

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

30. Since the last visit, has the patient taken any systemic corticosteroids:

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

31. Since the last visit, has the patient taken any cardiovascular/antihypertensive medications (If yes, check all that apply)

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

**32.**

- a. Amiodarone (Pacerone): ( 1 )
- b. Amlodipine besylate (Norvasc): ( 1 )
- c. Atenolol (Tenormin): ( 1 )
- d. Benazepril (Lotensin): ( 1 )
- e. Captopril (Capoten): ( 1 )
- f. Clonidine (Catapres): ( 1 )
- g. Digoxin (Lanoxin): ( 1 )
- h. Diltiazem (Cardizem): ( 1 )
- i. Doxazosin (Cardura): ( 1 )
- j. Enalapril (Vasotec): ( 1 )
- k. Felodipine (Plendil): ( 1 )
- l. Furosemide (Lasix): ( 1 )
- m. Hydrochlorothiazide (Esidrix, HydroDIURIL): ( 1 )
- n. Hydrochlorothiazide + triamterene (Dyazide): ( 1 )
- o. Lisinopril (Prinivil, Zestril): ( 1 )
- p. Losartan potassium (Cozaar): ( 1 )
- q. Losartan potassium with hydrochlorothiazide (Hyzaar): ( 1 )
- r. Metoprolol (Lopressor): ( 1 )
- s. Nifedipine (Adalat, Procardia): ( 1 )
- t. Perhexiline maleate: ( 1 )
- u. Propranolol (Inderal): ( 1 )
- v. Quinapril (Accupril): ( 1 )
- w. Terazosin (Hytrin): ( 1 )
- x. Timolol maleate (Blocadren): ( 1 )
- y. Valsartan (Diovan): ( 1 )
- z. Verapamil (Calan): ( 1 )
- aa. Other, (specify): ( 1 )

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

**32.** Since the last visit, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators  
(If yes, check all that apply)

- |                                 | Yes<br>( 1 )             | No<br>( 2 )              |
|---------------------------------|--------------------------|--------------------------|
|                                 | <b>33.</b>               | <input type="checkbox"/> |
| <b>a.</b> Oral contraceptives:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>b.</b> Raloxifene (Evista):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>c.</b> Tamoxifen (Nolvadex): | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>d.</b> Other, (specify):     | <input type="checkbox"/> | <input type="checkbox"/> |
- 

**33.** Since the last visit, has patient taken any of the following vitamins or supplements  
(If yes, check all that apply)

- |  | Yes<br>( 1 )             | No<br>( 2 )              |
|--|--------------------------|--------------------------|
|  | <b>34.</b>               | <input type="checkbox"/> |
| <b>a.</b> MultiVitamin:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>b.</b> Vitamin B (any type):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>c.</b> Vitamin C:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>d.</b> Vitamin D:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>e.</b> Vitamin E:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>f.</b> Alpha-lipoic acid:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>g.</b> Alpha-tocopherol:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>h.</b> Beta-carotene:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>i.</b> Betaine (Cystadane):   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>j.</b> Calcium (any form):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>k.</b> Carnitine (any form):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>l.</b> Choline + methionine + betaine + adenosine + pyridoxine (Epocler): | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>m.</b> Cod liver oil:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>n.</b> Coenzyme Q:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>o.</b> Echinacea:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>p.</b> Fish oil (any form):   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>q.</b> Flax seed oil:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>r.</b> Garlic:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>s.</b> Ginkgo biloba:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>t.</b> Glucosamine (any form):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>u.</b> Lecithin:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>v.</b> Milk thistle:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>w.</b> N-acetyl-cysteine:   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>x.</b> S-adenylmethionine (SAM-e):  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>y.</b> Saw palmetto:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>z.</b> Selenium:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>aa.</b> St. John's Wort:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>ab.</b> Taurine:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>ac.</b> Zinc picolinate:  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>ad.</b> Other, (specify):   | <input type="checkbox"/> | <input type="checkbox"/> |
-

**34.** Since the last visit, has patient taken any of the following medications or other supplements/medications  
(If yes, check all that apply)

Yes                      No  
 ( 1 )                      ( 2 )

**35.**

- a. Demeclocycline (Declomycin): ( 1 )
- b. Divalproex (Depakote): ( 1 )
- c. Doxycycline (Monodox): ( 1 )
- d. Isotretinoin (Accutane): ( 1 )
- e. Levothyroxine (Levoxyl, Synthroid): ( 1 )
- f. Liothyronine (Cytomel): ( 1 )
- g. Methotrexate (Rheumatrex): ( 1 )
- h. Minocycline (Dynacin, Minocin): ( 1 )
- i. Oxytetracycline (Terramycin): ( 1 )
- j. Tetracycline (Achromycin): ( 1 )
- k. Ursodeoxycholic acid (Actigall, Urso, Ursodiol): ( 1 )
- l. Valproate sodium (Depacon): ( 1 )
- m. Valproic acid (Depakene): ( 1 )
- n. Other, (specify): ( 1 )

\_\_\_\_\_ ( 1 )

**35.** Since the last visit, has patient taken any pain relieving, non-steroidal anti-inflammatory, aspirin, or acetaminophen-containing medications:

Yes                      No  
 ( 1 )                      ( 2 )

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

**36.** Subscores to compute Child-Pugh Turcotte score

- a. Rate the patient's ascites (check only one):
  - None ( 1 )
  - Mild, easily managed ( 2 )
  - Severe, refractory ( 3 )
- b. Rate the patient's hepatic encephalopathy (check only one):
  - None ( 1 )
  - Mild, easily managed ( 2 )
  - Severe, refractory ( 3 )

**I. Administrative information**

**37.** Study Physician PIN: \_\_\_\_\_

**38.** Study Physician signature: \_\_\_\_\_

**39.** Clinical Coordinator PIN: \_\_\_\_\_

**40.** Clinical Coordinator signature: \_\_\_\_\_

**41.** Date form reviewed: \_\_\_\_\_  
 day                      mon                      year

## NAFLD Database 2

## IE - Interim Event Report

**Purpose:** To document (1) events that occur after registration but before enrollment, or between regular follow-up visits, that impact on the patient's participation in the NAFLD Database 2 Study (eg, mild or moderate liver biopsy complications), or (2) other event that clinical center staff feel should be reported now rather than wait until the next follow-up visit and that is not recorded on another NAFLD Database 2 form.

**When:** As needed; use visit code n. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code n for first event, n1 for second event, etc.

**Administered by:** Study Physician and Clinical Coordinator.

**Instructions:** Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at [www.nashcrn.com](http://www.nashcrn.com). Click on Documents and then click on General Documents. Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).

**NASH CRN Data Coordinating Center telephone number:** (410) 955-8175.

**A. Center, patient, and visit identification**

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of report:  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

5. Visit code:  
 \_\_\_\_\_  
 n

6. Form & revision: \_\_\_\_\_  
 i e 1

7. Study: NAFLD Database 2 6

**B. Visit interval identification**

8. Most recently completed visit (screening or follow-up)

a. Date:  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

b. Visit code:  
 \_\_\_\_\_

**C. Patient information**

9. Date enrolled in NAFLD Database 2 Study (enter n if patient is not yet enrolled):  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

10. Gender:

Male ( )

Female ( )

11. Age at time of event: \_\_\_\_\_  
 years

**D. Event description**

12. Date event started:  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

13. Nature of event (check all that apply)

a. General anesthesia ( )

b. Study procedure related event: ( )

c. Drug interactions: ( )

d. Worsening of a co-morbid illness: ( )

e. Hypoglycemia: ( )

f. New-onset diabetes: ( )

g. Pregnancy (patient): ( )

h. Other (specify): ( )  
 \_\_\_\_\_  
 \_\_\_\_\_

14. Did the event lead to (check all that apply)

a. Emergency room visit: ( )

b. Hospitalization: ( )

c. Infectious episode: ( )

d. Surgical intervention: ( )

15. Describe event:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

20. Other comments on event:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

16. Short name for event if applicable (*short names for AEs are listed in the CTCAE v3.0 document available at www.nashcrn.com; click on Documents and then click on General Documents*):

Not applicable ( 0 )

\_\_\_\_\_  
\_\_\_\_\_

17. Severity grade (*severity grades are listed in the CTCAE v3.0 document available at www.nashcrn.com; click on Documents and then click on General Documents*):

Not applicable ( 0 )

Grade 1 - Mild ( 1 )

Grade 2 - Moderate ( 2 )

Grade 3 - Severe ( 3 )

Grade 4 - Life threatening or disabling ( 4 )

Grade 5 - Death ( \* 5 )

*\*Complete and key Death Report (DR) form.*

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

19. What action was taken:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

F. Administrative information

21. Clinical Coordinator PIN: \_\_\_\_\_

22. Clinical Coordinator signature: \_\_\_\_\_

23. Study Physician PIN: \_\_\_\_\_

24. Study Physician signature: \_\_\_\_\_

25. Date form reviewed:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

*Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.*

## NAFLD Database 2

## IE - Interim Event Report

**Purpose:** To document events that occur after registration that impact on the patient's participation in the NAFLD Database 2 Study (eg, mild or moderate liver biopsy complications). Complete this form if there has been an incident cirrhosis, hepatocellular carcinoma (HCC), hospitalization, Emergency Room visit, liver transplant, an event associated with a study-related procedure, or death.

**When:** As needed; use visit code n. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code n for first event, n1 for second event, etc.

**Administered by:** Study Physician and Clinical Coordinator.

**Instructions:** Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at <https://jhucce1.us/nash/default.asp>. Click on Documents and then click on General Documents. **Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).**

**NASH CRN Data Coordinating Center telephone number:** (410) 955-8175.

## A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of report: \_\_\_\_\_

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

5. Visit code: \_\_\_\_\_

n \_\_\_\_\_

6. Form & revision: i e 2

7. Study: NAFLD Database 2 6

## B. Visit interval identification

8. Most recently completed visit (screening or follow-up)

a. Date:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

b. Visit code: \_\_\_\_\_

## C. Patient information

9. Date enrolled in NAFLD Database 2 Study (*enter n if patient is not yet enrolled*):

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

10. Gender:

Male ( 1 )

Female ( 2 )

11. Age at time of event: \_\_\_\_\_ years

## D. Event description

12. Date event started: \_\_\_\_\_

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

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

a. General anesthesia ( 1 )

b. Study-related procedure: ( 1 )

c. Drug interactions: ( 1 )

d. Worsening of a co-morbid illness: ( 1 )

e. Hypoglycemia: ( 1 )

f. New-onset diabetes: ( 1 )

g. Pregnancy (*patient*): ( 1 )

h. Cirrhosis: ( 1 )

i. Hepatocellular carcinoma (HCC): ( \* 1 )  
\* Complete and key the HC form.

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

\_\_\_\_\_  
\_\_\_\_\_

**14. Did the event lead to (check all that apply)**

- a. Emergency room visit: (  )
- b. Hospitalization: (  )
- c. Infectious episode: (  )
- d. Surgical intervention: (  )

**15. Describe event:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**16. Indicate the name for the event obtained from the NCI's Common Terminology Criteria for Adverse Events (CTCAE v3.0 document available at <https://jhucsc1.us/nash/default.asp>; click on Documents and then click on General Documents):**

\_\_\_\_\_

\_\_\_\_\_

- a. Not in CTCAE (e.g. malignancy, data breach) (specify): (  )

\_\_\_\_\_

\_\_\_\_\_

**17. Indicate the severity code using the CTCAE grading scale for the AE specified (severity grades are listed in the CTCAE v3.0 document available at <https://jhucsc1.us/nash/default.asp>; click on Documents and then click on General Documents):**

- Grade 1 - Mild (  )
- Grade 2 - Moderate (  )
- Grade 3 - Severe† (  )
- Grade 4 - Life threatening or disabling† (  )
- Grade 5 - Death† ( \*  )

†Fax the DCC (Attention Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).

\*Complete and key Death Report (DR) form.

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

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

**19. What action was taken:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**20. Other comments on event:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**F. Administrative information**

**21. Clinical Coordinator PIN:** \_\_\_\_\_

**22. Clinical Coordinator signature:**

\_\_\_\_\_

**23. Study Physician PIN:** \_\_\_\_\_

**24. Study Physician signature:**

\_\_\_\_\_

**25. Date form reviewed:**

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.*





**14.** Did the event lead to (*check all that apply*)

- a. Emergency room visit: (  )
- b. Hospitalization: (  )
- c. Infectious episode: (  )
- d. Surgical intervention: (  )

**15.** Describe event:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**16.** Is the event listed in the NCI's Common Terminology Criteria for Adverse Events (CTCAE v3.0 document available at <https://jhucss1.us/nash/default.asp>; click on Documents and then click on General Documents):

- Yes (  )      No (  )

a. Indicate the name of the event (if in the CTCAE, specify name exactly from document; if not in CTCAE specify name):

\_\_\_\_\_

\_\_\_\_\_

**17.** Indicate the severity code using the CTCAE grading scale for the AE specified (*severity grades are listed in the CTCAE v3.0 document available at <https://jhucss1.us/nash/default.asp>; click on Documents and then click on General Documents*):

- Grade 1 - Mild (  )
- Grade 2 - Moderate (  )
- Grade 3 - Severe† (  )
- Grade 4 - Life threatening or disabling† (  )
- Grade 5 - Death† ( \*  )

†Fax the DCC (Attention Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).

\*Complete and key Death Report (DR) form.

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

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day                      mon                      year

**19.** What action was taken:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**20.** Other comments on event:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**F. Administrative information**

**21.** Clinical Coordinator PIN: \_\_\_\_\_

**22.** Clinical Coordinator signature:  
\_\_\_\_\_

**23.** Study Physician PIN: \_\_\_\_\_

**24.** Study Physician signature:  
\_\_\_\_\_

**25.** Date form reviewed:  
\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day                      mon                      year

*Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious events so that we assure appropriate and timely study wide review. The received reports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitoring Board.*

## NAFLD Database 2

## IR - Liver Imaging Studies Report

**Purpose:** To record liver imaging study results.

**When:** As needed during screening (visit t0) and follow-up (visits t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480).

**Administered by:** Clinical Coordinator.

**Instructions:** Complete this form at each of the visits listed above if the Baseline Medical History (BG) or Follow-up Medical History (HI) form says that a liver imaging study was obtained in the specified period. The form will allow you to skip out of sections that are irrelevant to your patient. What you will report at each visit are the results of the most recent scan of each type done in the 6 months prior to screening (visit t0) or in the period since the prior study visit (after enrollment). These will likely be standard of care scans with results obtained via medical records. In each case, answer the items based on review of the report; the Study Physician must review and approve the findings recorded on this form.

### A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_
2. Patient ID: \_\_\_\_\_
3. Patient code: \_\_\_\_\_
4. Date of visit:  
 \_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year
5. Visit code: \_\_\_\_\_
6. Form & revision:   i     r     1
7. Study: NAFLD Database 2   6

### B. Upper abdominal ultrasound

8. Did the patient have an upper abdominal ultrasound in the past 6 months (*screening*)/since the last visit (*follow-up*):

(<sup>Yes</sup>  
( 1 )      (<sup>No</sup>  
( 2 )

**11.**

9. Date of most recent upper abdominal ultrasound:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

10. Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance (*check all that apply*)

- a. Fatty infiltration: ( 1 )
- b. Cirrhosis: ( 1 )
- c. Hepatomegaly: ( 1 )
- d. Hepatic mass: ( 1 )
- e. Intrahepatic biliary dilatation: ( 1 )
- f. Extrahepatic biliary dilatation: ( 1 )
- g. Gallstones/cholelithiasis: ( 1 )
- h. Gall bladder polyps: ( 1 )
- i. Cholecystectomy: ( 1 )
- j. Splenomegaly: ( 1 )
- k. Ascites: ( 1 )
- l. Other features of portal hypertension (*specify*): ( 1 )  
 \_\_\_\_\_  
 \_\_\_\_\_
- m. Other abnormality (*specify*): ( 1 )  
 \_\_\_\_\_  
 \_\_\_\_\_
- n. None of the above: ( 1 )

**C. Upper abdominal CT scan**

**11.** Did the patient have an upper abdominal CT scan in the past 6 months (*screening*)/  
since the last visit (*follow-up*):

Yes ( 1 )      No ( 2 )  
        
**14.**

**12.** Date of most recent upper abdominal CT scan:

\_\_\_\_\_  
 day                  mon                  year

**13.** Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance (*check all that apply*)

- a. Fatty infiltration: ( 1 )
- b. Cirrhosis: ( 1 )
- c. Hepatomegaly: ( 1 )
- d. Hepatic mass: ( 1 )
- e. Hepatic hemangioma: ( 1 )
- f. Hepatic cyst: ( 1 )
- g. Intrahepatic biliary dilatation: ( 1 )
- h. Extrahepatic biliary dilatation: ( 1 )
- i. Gallstones/cholelithiasis: ( 1 )
- j. Gall bladder polyps: ( 1 )
- k. Cholecystectomy: ( 1 )
- l. Splenomegaly: ( 1 )
- m. Ascites: ( 1 )
- n. Other features of portal hypertension (*specify*): ( 1 )  
\_\_\_\_\_  
\_\_\_\_\_
- o. Other abnormality (*specify*): ( 1 )  
\_\_\_\_\_  
\_\_\_\_\_
- p. None of the above: ( 1 )

**D. Upper abdominal MRI**

**14.** Did the patient have an upper abdominal MRI in the past 6 months (*screening*)/  
since the last visit (*follow-up*):

Yes ( 1 )      No ( 2 )  
        
**17.**

**15.** Date of most recent upper abdominal MRI:

\_\_\_\_\_  
 day                  mon                  year

**16.** Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance (*check all that apply*)

- a. Fatty infiltration: ( 1 )
- b. Cirrhosis: ( 1 )
- c. Hepatomegaly: ( 1 )
- d. Hepatic mass: ( 1 )
- e. Hepatic hemangioma: ( 1 )
- f. Hepatic cyst: ( 1 )
- g. Intrahepatic biliary dilatation: ( 1 )
- h. Extrahepatic biliary dilatation: ( 1 )
- i. Splenomegaly: ( 1 )
- j. Ascites: ( 1 )
- k. Other features of portal hypertension (*specify*): ( 1 )  
\_\_\_\_\_  
\_\_\_\_\_
- l. Other abnormality (*specify*): ( 1 )  
\_\_\_\_\_  
\_\_\_\_\_
- m. None of the above: ( 1 )

**E. Administrative information**

17. Study Physician PIN: \_\_\_\_\_

18. Study Physician signature:  
\_\_\_\_\_

19. Clinical Coordinator PIN: \_\_\_\_\_

20. Clinical Coordinator signature:  
\_\_\_\_\_

21. Date form reviewed:  
\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day mon year

## NAFLD Database 2

LD – Lifetime Drinking History  
(Skinner)

**Purpose:** To obtain quantitative indices of the patient's alcohol consumption patterns from the onset of regular drinking.

**When:** Visit t0. If more than one LD form is needed, use visit code "n" on the second LD form.

**Administered by:** Clinical Coordinator.

**Respondent:** New Database 2 Patients, 18 years of age or older, without help from spouse or family.

**Instructions:** **Complete this form for new Database 2 patients only.** In addition to actual consumption levels (quantity), attention is focused upon the frequency of use, variability in consumption, types of beverages, life events that mark a change in drinking pattern, solitary versus social drinking, and time of day when alcohol is consumed. Flash Card #9, Drink Equivalents, may be used with this interview.

The interviewer begins by recording the patient's alcohol consumption behavior during the first year that he/she drank on a regular basis (at least one drink per month). Then, the patient is asked to think of when his/her drinking behavior changed in any appreciable way. In a chronological fashion, the interviewer traces the patient's alcohol consumption behavior from the age of first regular drinking to the present. Flash Card #10, Patterns of Alcohol Intake, provides sample language for the interviewer. Each LD form allows for describing six drinking phases. Use a second LD form (visit code "n") if needed to describe additional drinking phases. If this is the second LD form, skip sections B and C and start with item 20.

The interview takes approximately 20 minutes to complete. It is best given after a reasonable degree of rapport has been established, whereby the patient will feel more at ease and talk openly. Other, considerable probing and cross-referencing of facts is necessary to help in accurate recall. All information should be recorded under the appropriate heading on the LD form.

## A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

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

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
day mon year

5. Visit code: \_\_\_\_\_

6. Form & revision:   1     d     1  

7. Study: NAFLD Database 2   6  

## B. Lifetime alcohol consumption

8. Over the course of your lifetime have you ever had at least one drink of alcohol, beer, liquor, wine, or wine coolers, per month during a 12-month time period, or at least three drinks per day for at least three consecutive days (over a regular period of time):

Yes      No  
( 1 )    ( 2 )  
81. ←

**C. First phase**

**Read as written:** "Now, I am going to ask you about your drinking pattern during the first year that you began to have at least one drink per month until your drinking behavior was different in a significant way from this time."

9. How old were you when you began regular drinking:

a. Years: \_\_\_\_\_ yrs

b. Months: \_\_\_\_\_ mos

10. How old were you at the end of first stage:

a. Years: \_\_\_\_\_ yrs

b. Months: \_\_\_\_\_ mos

11. During the first stage, how many drinks would you have on average per occasion (*drinking day*):

\_\_\_\_\_ # drinks

12. How many days per month would you generally drink at this level:

\_\_\_\_\_ # days

13. What is the most or maximum number of drinks you would have in any one day:

\_\_\_\_\_ # drinks

*(Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.)*

14. What type of beverage would you usually consume in an average month (*record the relative percentages of beer, liquor or wine; this section should add up to 100%*):

Beer \_\_\_\_\_ %

Liquor \_\_\_\_\_ %

Wine \_\_\_\_\_ %

15. How would you rate your usual style of drinking during an average month (*check the appropriate category*):

- Abstinent ( 1 )
- Occasional (*less than 15 days*) ( 2 )
- Weekend mainly ( 3 )
- Binge (*at least 3 days heavy drinking*) ( 4 )
- Frequent (*15 days or more per month*) ( 5 )

16. Did any important event or events occur during this period that altered your usual drinking habits:

Yes ( 1 ) No ( 2 )

**18.** ←

17. What was your perception of this event? Would you say that it had a positive (desirable), negative (undesirable), or neutral (no) effect on your life (*for each event that influenced the patient's drinking pattern, check "1" for positive effect or "2" for negative effect or "3" for neutral or no effect*):

	Positive	Negative	Neutral
a. Marital/family ..	( 1 )	( 2 )	( 3 )
b. Work .....	( 1 )	( 2 )	( 3 )
c. School .....	( 1 )	( 2 )	( 3 )
d. Medical .....	( 1 )	( 2 )	( 3 )
e. Residence .....	( 1 )	( 2 )	( 3 )
f. Legal/jail .....	( 1 )	( 2 )	( 3 )
g. Financial .....	( 1 )	( 2 )	( 3 )
h. Peer group .....	( 1 )	( 2 )	( 3 )
i. Drug abuse .....	( 1 )	( 2 )	( 3 )
j. Treatment .....	( 1 )	( 2 )	( 3 )
k. Death .....	( 1 )	( 2 )	( 3 )
l. Emotional .....	( 1 )	( 2 )	( 3 )

18. What percentage of time would you drink alone, and what percentage of the time with at least one other person (*record the relative percentages of "Alone" and "With others"; this section should add up to 100%*):

Alone \_\_\_\_\_ %

With others \_\_\_\_\_ %

19. During what time of the day would you do most of your drinking? Could you give me the percentage of time during the evening, afternoon and morning (*record the relative percentages of morning, afternoon and evening; this section should add up to 100%; if not drinking, percentages should all be "000"*):

Morning \_\_\_\_\_ %

Afternoon \_\_\_\_\_ %

Evening \_\_\_\_\_ %

**D. Subsequent phase**

20. **Read as written:** "We have just discussed your drinking habits at the point when you first began to drink regularly. Now I want you to think to when your drinking behavior was different in a significant way from this time. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits":

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

( 1 ) ( 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 No

( 1 ) ( 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                  No  
 ( 1 )                ( 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                  No  
 ( 1 )                ( 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
<b>a.</b> Marital/family ..	( 1 )	( 2 )	( 3 )
<b>b.</b> Work .....	( 1 )	( 2 )	( 3 )
<b>c.</b> School .....	( 1 )	( 2 )	( 3 )
<b>d.</b> Medical .....	( 1 )	( 2 )	( 3 )
<b>e.</b> Residence .....	( 1 )	( 2 )	( 3 )
<b>f.</b> Legal/jail .....	( 1 )	( 2 )	( 3 )
<b>g.</b> Financial .....	( 1 )	( 2 )	( 3 )
<b>h.</b> Peer group .....	( 1 )	( 2 )	( 3 )
<b>i.</b> Drug abuse .....	( 1 )	( 2 )	( 3 )
<b>j.</b> Treatment .....	( 1 )	( 2 )	( 3 )
<b>k.</b> Death .....	( 1 )	( 2 )	( 3 )
<b>l.</b> Emotional .....	( 1 )	( 2 )	( 3 )



## NAFLD Database 2

LR - Laboratory Results - Tests Done During  
Screening and Follow-up

**Purpose:** To record archival and current laboratory test results for tests done during both screening and follow-up.

**When:** Visits t0, t048, t096, t144, and t192.

**Administered by:** Study Physician and Clinical Coordinator.

**Instructions:** All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

**A. Center, patient, and visit identification**

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of visit (*date form was initiated*):

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

5. Visit code: t \_\_\_\_\_

6. Form & revision: 1 r 1

7. Study: NAFLD Database 2 6

**B. Hematology**

8. Date of blood draw for complete blood count:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

9. Hemoglobin: \_\_\_\_\_ g/dL

10. Hematocrit: \_\_\_\_\_ %

11. Mean corpuscular volume (MCV):

\_\_\_\_\_ fL

12. White blood cell count (WBC):

\_\_\_\_\_  $10^3$  cells/ $\mu$ L or  $10^9$  cells/L

13. Platelet count:

\_\_\_\_\_, \_\_\_\_\_ cells/ $\mu$ L

**C. Chemistries and HbA1c**

14. Date of blood draw for chemistries:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

15. Blood urea nitrogen (BUN): \_\_\_\_\_ mg/dL

16. Creatinine: \_\_\_\_\_ mg/dL

17. Uric acid: \_\_\_\_\_ mg/dL

18. Date of blood draw for HbA1c:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

19. HbA1c: \_\_\_\_\_ %

**D. Liver panel**

20. Date of blood draw for liver panel:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

21. Bilirubin (total): \_\_\_\_\_ mg/dL

22. Bilirubin (direct): \_\_\_\_\_ mg/dL

23. Aspartate aminotransferase (AST)  
 \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

24. Alanine aminotransferase (ALT)  
 \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

25. Alkaline phosphatase  
 \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

26. Gamma glutamyl transferase (GGT):  
 \_\_\_\_\_ U/L

27. Total protein: \_\_\_\_\_ g/dL

28. Albumin: \_\_\_\_\_ g/dL

29. Prothrombin time (PT): \_\_\_\_\_ sec

30. International normalized ratio (INR):  
 \_\_\_\_\_

**E. Fasting lipid profile**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.*

31. Was participant fasting for at least 8 hours prior to blood draw:  
 (Yes) (No\*)  
 ( 1 ) ( \* 2 )

*\*12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:  
 \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

a. Triglycerides: \_\_\_\_\_ mg/dL

b. Total cholesterol: \_\_\_\_\_ mg/dL

c. HDL cholesterol: \_\_\_\_\_ mg/dL

d. LDL cholesterol: \_\_\_\_\_ mg/dL

**F. Fasting glucose and insulin**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.*

33. Was participant fasting for at least 8 hours prior to blood draw:  
 (Yes) (No\*)  
 ( 1 ) ( \* 2 )

35. \_\_\_\_\_

*\*Patient must be fasting; 12 hour fast is preferred.*

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

*Date must be within the required time window; within 3 months of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.*

a. Serum glucose: \_\_\_\_\_  
mg/dL

b. Serum insulin: \_\_\_\_\_  
μU/mL

**G. Administrative information**

35. Study Physician PIN: \_\_\_\_\_

36. Study Physician signature:  
\_\_\_\_\_

37. Clinical Coordinator PIN: \_\_\_\_\_

38. Clinical Coordinator signature:  
\_\_\_\_\_

39. Date form reviewed:  
\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year



## NAFLD Database 2

LR - Laboratory Results - Tests Done During  
Screening and Follow-up

**Purpose:** To record archival and current laboratory test results for tests done during both screening and follow-up.

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

**Administered by:** Study Physician and Clinical Coordinator.

**Instructions:** All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

## A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of visit (*date form was initiated*):

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

5. Visit code: t \_\_\_\_\_

6. Form & revision: 1 r 2

7. Study: NAFLD Database 2 6

## B. Hematology

8. Date of blood draw for complete blood count:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

9. Hemoglobin: \_\_\_\_\_ g/dL

10. Hematocrit: \_\_\_\_\_ %

11. Mean corpuscular volume (MCV):

\_\_\_\_\_ fL

12. White blood cell count (WBC):

\_\_\_\_\_  $10^3$  cells/ $\mu$ L or  $10^9$  cells/L

13. Platelet count:

\_\_\_\_\_ cells/ $\mu$ L

## C. Chemistries and HbA1c

14. Date of blood draw for chemistries:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

15. Blood urea nitrogen (BUN): \_\_\_\_\_ mg/dL

16. Creatinine: \_\_\_\_\_ mg/dL

17. Uric acid: \_\_\_\_\_ mg/dL

18. Date of blood draw for HbA1c:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

19. HbA1c: \_\_\_\_\_ %

**D. Liver panel**

20. Date of blood draw for liver panel:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

21. Bilirubin (total): \_\_\_\_\_ mg/dL

22. Bilirubin (direct): \_\_\_\_\_ mg/dL

23. Aspartate aminotransferase (AST)  
 \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

24. Alanine aminotransferase (ALT)  
 \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

25. Alkaline phosphatase \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

26. Gamma glutamyl transferase (GGT): \_\_\_\_\_ U/L

27. Total protein: \_\_\_\_\_ g/dL

28. Albumin: \_\_\_\_\_ g/dL

29. Prothrombin time (PT): \_\_\_\_\_ sec

30. International normalized ratio (INR): \_\_\_\_\_

**E. Fasting lipid profile**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.*

31. Was participant fasting for at least 8 hours prior to blood draw:  
 (Yes 1) (No\* 2)

*\*12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:  
 \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

a. Triglycerides: \_\_\_\_\_ mg/dL

b. Total cholesterol: \_\_\_\_\_ mg/dL

c. HDL cholesterol: \_\_\_\_\_ mg/dL

d. LDL cholesterol\*: \_\_\_\_\_ mg/dL

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

**F. Fasting glucose and insulin**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.*

33. Was participant fasting for at least 8 hours prior to blood draw:  
 (Yes 1) (No\* 2)

35. \_\_\_\_\_

*\*Patient must be fasting; 12 hour fast is preferred.*

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.*

a. Serum glucose: \_\_\_\_\_  
mg/dL

b. Serum insulin: \_\_\_\_\_  
μU/mL

**G. Administrative information**

35. Study Physician PIN: \_\_\_\_\_

36. Study Physician signature:  
\_\_\_\_\_

37. Clinical Coordinator PIN: \_\_\_\_\_

38. Clinical Coordinator signature:  
\_\_\_\_\_

39. Date form reviewed:  
\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

## NAFLD Database 2

LR - Laboratory Results - Tests Done During  
Screening and Follow-up

**Purpose:** To record archival and current laboratory test results for tests done during both screening and follow-up.

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

**Administered by:** Study Physician and Clinical Coordinator.

**Instructions:** All laboratory test results are required during screening. Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

**A. Center, patient, and visit identification**

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of visit (*date form was initiated*):

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

5. Visit code: t \_\_\_\_\_6. Form & revision: 1 r 37. Study: NAFLD Database 2 6**B. Hematology**

8. Date of blood draw for complete blood count:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

9. Hemoglobin: \_\_\_\_\_  
g/dL10. Hematocrit: \_\_\_\_\_  
%11. Mean corpuscular volume (MCV): \_\_\_\_\_  
fL**12. Blood cell count**

a. White blood cell count (WBC):

\_\_\_\_\_  
 10<sup>3</sup> cells/ $\mu$ L or 10<sup>9</sup> cells/L

b. Red blood cell count (RBC):

\_\_\_\_\_  
 mill cells/ $\mu$ L

**13. Platelet count:**

\_\_\_\_\_, \_\_\_\_\_  
 cells/ $\mu$ L

**C. Chemistries and HbA1c**

14. Date of blood draw for chemistries:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

15. Blood urea nitrogen (BUN): \_\_\_\_\_  
mg/dL16. Creatinine: \_\_\_\_\_  
mg/dL17. Uric acid: \_\_\_\_\_  
mg/dL

18. Date of blood draw for HbA1c:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

19. HbA1c: \_\_\_\_\_  
%

**D. Liver panel**

20. Date of blood draw for liver panel:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

21. Bilirubin (total): \_\_\_\_\_ ● \_\_\_\_\_  
 mg/dL

22. Bilirubin (direct)\*: \_\_\_\_\_ ● \_\_\_\_\_  
 mg/dL

*\*If result is <0.2 or <0.1, record 00.1 and indicate the actual result in a comment.*

23. Aspartate aminotransferase (AST)

\_\_\_\_ U/L \_\_\_\_\_

a. Upper limit of normal: \_\_\_\_\_ U/L

24. Alanine aminotransferase (ALT)

\_\_\_\_ U/L \_\_\_\_\_

a. Upper limit of normal: \_\_\_\_\_ U/L

25. Alkaline phosphatase \_\_\_\_\_ U/L

a. Upper limit of normal: \_\_\_\_\_ U/L

26. Gamma glutamyl transferase (GGT):

\_\_\_\_ U/L \_\_\_\_\_

27. Total protein: \_\_\_\_\_ ● \_\_\_\_\_  
 g/dL

28. Albumin: \_\_\_\_\_ ● \_\_\_\_\_  
 g/dL

29. Prothrombin time (PT): \_\_\_\_\_ ● \_\_\_\_\_  
 sec

30. International normalized ratio (INR):

\_\_\_\_\_ ● \_\_\_\_\_

**E. Fasting lipid profile**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.*

31. Was participant fasting for at least 8 hours prior to blood draw:  
 Yes ( 1 ) No ( \* 2 )

*\*12 hour fasting is preferred, but will accept non-fasting lipid values.*

32. Date of blood draw for lipid profile:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide).*

a. Triglycerides: \_\_\_\_\_ mg/dL

b. Total cholesterol: \_\_\_\_\_ mg/dL

c. HDL cholesterol: \_\_\_\_\_ mg/dL

d. LDL cholesterol\*: \_\_\_\_\_ mg/dL

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

**F. Fasting glucose and insulin**

*Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw. These tests are required during screening.*

33. Was participant fasting for at least 8 hours prior to blood draw:  
 Yes ( 1 ) No ( \* 2 )

35. \_\_\_\_\_

*\*Patient must be fasting; 12 hour fast is preferred.*

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

\_\_\_\_ day      \_\_\_\_ mon      \_\_\_\_ year

*Date must be within the required time window; within 90 days of screening or in the time window for the follow-up visit (check the patient's Database 2 visit time window guide). The serum glucose and insulin value should be obtained from the same blood draw.*

**a.** Serum glucose: \_\_\_\_\_ mg/dL

**b.** Serum insulin: \_\_\_\_\_  $\mu$ U/mL

**G. Administrative information**

**35.** Study Physician PIN: \_\_\_\_\_

**36.** Study Physician signature:  
\_\_\_\_\_

**37.** Clinical Coordinator PIN: \_\_\_\_\_

**38.** Clinical Coordinator signature:  
\_\_\_\_\_

**39.** Date form reviewed:  
\_\_\_\_ day      \_\_\_\_ mon      \_\_\_\_ year



**e. Hepatitis C virus RNA:**

Positive

( 1 )

Negative

( 2 )

Not available

( 3 )

**f. Hepatitis A virus antibody  
(anti-HAV, total):**

Positive

( 1 )

Negative

( 2 )

Not available

( 3 )

**C. Iron**

**11. Date of blood draw for iron overload screening:**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

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

**a. Iron:**

\_\_\_\_\_  $\mu\text{g/dL}$

**b. Total iron binding capacity:**

\_\_\_\_\_  $\mu\text{g/dL}$

**c. Ferritin:**

\_\_\_\_\_  $\text{ng/mL}$

**12. Is hepatic iron index available:**

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

**14.** \_\_\_\_\_

**13. Hepatic iron index:**

\_\_\_\_\_  $\mu\text{Mol/g/year}$

**D. HFE gene analysis**

**14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:**

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

**17.** \_\_\_\_\_

**15. Date of blood draw for HFE gene analysis:**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

**16. Type of abnormality (WT = wild type; check only one):**

- None ( 0 )
- C282Y/H63D heterozygote mutation ( 1 )
- C282Y/C282Y homozygote mutation ( 2 )
- C282Y/WT heterozygote mutation ( 3 )
- H63D/WT heterozygote mutation ( 4 )
- H63D/H63D homozygote mutation ( 5 )

**E. Ceruloplasmin**

**17. Is patient 40 years old or younger:**

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

**20.** \_\_\_\_\_

**18. Date of blood draw for ceruloplasmin: (required only if patient is 40 years old or younger):**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

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

**19. Ceruloplasmin**

\_\_\_\_\_  $\text{mg/dL}$

**a. Upper limit of normal:**

\_\_\_\_\_  $\text{mg/dL}$

**b. Lower limit of normal:**

\_\_\_\_\_  $\text{mg/dL}$



**F. Alpha-1 antitrypsin**

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

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

21. Alpha-1 antitrypsin (A1AT) \_\_\_\_\_ mg/dL

a. Upper limit of normal: \_\_\_\_\_ mg/dL

b. Lower limit of normal: \_\_\_\_\_ mg/dL

22. A1AT phenotype:

a. Pi Z heterozygote:  
 Yes ( 1 )  
 No ( 2 )  
 Unknown ( 3 )

b. Pi ZZ homozygote:  
 Yes ( 1 )  
 No ( 2 )  
 Unknown ( 3 )

23. A1AT deficiency (physician judgment):

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 **Elig**

**G. Autoantibody studies**

24. Date of blood draw for autoantibody tests:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

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

25. Antinuclear antibody (ANA):

Positive ( \* )  
 Negative ( 2 )  
**26.**

*\*If positive ANA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

26. Antismooth muscle antibody (ASMA):

Positive ( \* )  
 Negative ( 2 )

**27.**

*\*If positive ASMA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

27. Antimitochondrial antibody (AMA):

Positive ( \* )  
 Negative ( 2 )

**28.**

Age < 18 and not done ( 3 )

**28.**

*\*If positive AMA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

\_\_\_\_\_

b. Units: \_\_\_\_\_

28. Is patient 18 or older:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
**32.**

29. Lymphocytotoxic antibody (LCA):

Positive ( \* )  
 Negative ( 2 )

**30.**

Not available ( 3 )

**30.**

*\*If positive LCA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

\_\_\_\_\_

b. Units: \_\_\_\_\_

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

Positive ( \* )

Negative ( 2 )

Not available ( 3 )

31.

31.

*\*If positive LKM1 value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_ • \_\_\_\_\_

31. Rheumatoid factor (RF):

Positive ( \* )

Negative ( 2 )

Not available ( 3 )

32.

32.

*\*If positive, record RF value.*

a. Units: \_\_\_\_\_ • \_\_\_\_\_  
IU/mL

*If results are given as a titer, record as "n" and key the actual result in the General Comments.*

**H. Immunoglobulin levels**

32. Are immunoglobulin levels available:

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

37.

33. Date of blood draw for immunoglobulin levels:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

34. IgA: \_\_\_\_\_  
mg/dL

35. IgG: \_\_\_\_\_  
mg/dL

36. IgM: \_\_\_\_\_  
mg/dL

**I. Other screening blood tests**

37. Date of blood draw for thyroid stimulating hormone (TSH)\*:

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

*Repeat if date is greater than 5 years prior to screening. \*Optional if patient under age 18; enter "m" if not done.*

38. Thyroid stimulating hormone:

\_\_\_\_\_ • \_\_\_\_\_  
μU/mL

**J. Administrative information**

39. Study Physician PIN: \_\_\_\_\_

40. Study Physician signature: \_\_\_\_\_

41. Clinical Coordinator PIN: \_\_\_\_\_

42. Clinical Coordinator signature: \_\_\_\_\_

43. Date form reviewed:  
\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

## NAFLD Database 2

## LS - Laboratory Results - Tests Done only During Screening

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

**When:** Visit t0.

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

**Instructions:**

**New Database 2 patients:** All laboratory test results are required at screening.

**Continuing Database 2 patients:** Laboratory tests may be repeated if clinically indicated.

Laboratory test results may be obtained from chart review. The acceptable time interval for archival laboratory data is specified for each test and recorded next to the date of blood draw. Laboratory tests should be repeated if the blood draw date is outside the specified time interval. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form. If  is checked for any item, you do not need to complete the rest of the form and the form should not be keyed.

### A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Date of visit:  
 \_\_\_\_\_  
                   day                  mon                  year

5. Visit code: t 0 \_\_\_\_\_

6. Form & revision: 1 s 2

7. Study: NAFLD Database 2 6

8. Is the patient a continuing participant from Database, PIVENS, or TONIC:  
   Yes  No  
   ( )  ( \* )  
   1  2

**10.** *\*All laboratory test results are required during screening.*

9. Are new laboratory results available for the continuing participant:  
   Yes  No  
   ( \* )  ( )  
   1  2

**39.** *\*Record the date of blood draw as "m" if a test was not done.*

### B. Screening etiologic tests

10. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                                   day                                  mon                                  year

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

*If the patient is judged by Study Physician to have a high-risk lifestyle, repeat if date is greater than 6 months prior to screening.*

a. Hepatitis B surface antigen (HBsAg):

Positive  ( 1 )

Negative ( 2 )

b. Hepatitis B core total antibody (anti-HBc) (if total anti-HBc is not available, record results from IgG test):

Positive ( 1 )

Negative ( 2 )

Not available ( 3 )

c. Hepatitis B surface antibody (anti-HBs):

Positive ( 1 )

Negative ( 2 )

Not available ( 3 )

d. Hepatitis C antibody (anti-HCV) (indicate result as negative if EIA is positive but RIBA is negative or if RIBA is indeterminate or unavailable but HCV RNA is negative):

Positive  ( 1 )

Negative ( 2 )

**e. Hepatitis C virus RNA:**

- Positive  ( 1 )
- Negative  ( 2 )
- Not available  ( 3 )

**f. Hepatitis A virus antibody  
(anti-HAV, total):**

- Positive  ( 1 )
- Negative  ( 2 )
- Not available  ( 3 )

**C. Iron**

**11. Date of blood draw for iron overload screening:**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year  
*Repeat if date is greater than 5 years prior to screening.*

**a. Iron:** \_\_\_\_\_  $\mu\text{g/dL}$

**b. Total iron binding capacity:** \_\_\_\_\_  $\mu\text{g/dL}$

**c. Ferritin:** \_\_\_\_\_  $\text{ng/mL}$

**12. Is hepatic iron index available:**

- ( Yes ) ( No )  
 ( 1 )  ( 2 )  
**14.** \_\_\_\_\_

**13. Hepatic iron index:**

\_\_\_\_\_  $\mu\text{Mol/g/year}$

**D. HFE gene analysis**

**14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:**

- ( Yes ) ( No )  
 ( 1 )  ( 2 )  
**17.** \_\_\_\_\_

**15. Date of blood draw for HFE gene analysis:**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year

**16. Type of abnormality (WT = wild type; check only one):**

- None  ( 0 )
- C282Y/H63D heterozygote mutation  ( 1 )
- C282Y/C282Y homozygote mutation  ( 2 )
- C282Y/WT heterozygote mutation  ( 3 )
- H63D/WT heterozygote mutation  ( 4 )
- H63D/H63D homozygote mutation  ( 5 )

**E. Ceruloplasmin**

**17. Is patient 40 years old or younger:**

- ( Yes ) ( No )  
 ( 1 )  ( 2 )  
**18.** \_\_\_\_\_

**a. Is a ceruloplasmin value available:**

- ( Yes ) ( No )  
 ( 1 )  ( 2 )  
**20.** \_\_\_\_\_

**18. Date of blood draw for ceruloplasmin: (required only if patient is 40 years old or younger; record if available if patient is greater than 40 years old):**

\_\_\_\_\_ day \_\_\_\_\_ mon \_\_\_\_\_ year  
*Repeat if date is greater than 10 years prior to screening.*

**19. Ceruloplasmin** \_\_\_\_\_  $\text{mg/dL}$

**a. Upper limit of normal:** \_\_\_\_\_  $\text{mg/dL}$

**b. Lower limit of normal:** \_\_\_\_\_  $\text{mg/dL}$

**F. Alpha-1 antitrypsin**

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

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

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

21. Alpha-1 antitrypsin (A1AT) \_\_\_\_\_ mg/dL

a. Upper limit of normal: \_\_\_\_\_ mg/dL

b. Lower limit of normal: \_\_\_\_\_ mg/dL

22. A1AT phenotype:

a. Pi Z heterozygote:  
 Yes ( 1 )  
 No ( 2 )  
 Unknown ( 3 )

b. Pi ZZ homozygote:  
 Yes ( 1 )  
 No ( 2 )  
 Unknown ( 3 )

23. A1AT deficiency (physician judgment):

( Yes ) ( No )  
 ( 1 ) ( 2 )  
 **Elig**

**G. Autoantibody studies**

24. Date of blood draw for autoantibody tests:

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
 day mon year

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

25. Antinuclear antibody (ANA):

Positive ( \* )  
 Negative ( 2 )  
**26.**

*\*If positive ANA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

26. Antismooth muscle antibody (ASMA):

Positive ( \* )  
 Negative ( 2 )  
**27.**

*\*If positive ASMA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

27. Antimitochondrial antibody (AMA):

Positive ( \* )  
 Negative ( 2 )  
 Age < 18 and not done ( 3 )  
**28.**

*\*If positive AMA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

28. Is patient 18 or older:

( Yes ) ( No )  
 ( 1 ) ( 2 )  
**32.**

29. Lymphocytotoxic antibody (LCA):

Positive ( \* )  
 Negative ( 2 )  
 Not available ( 3 )  
**30.**

*\*If positive LCA value, complete either a or b depending on laboratory results:*

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_

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

- Positive ( \*<sub>1</sub> )  
 Negative ( <sub>2</sub> )  
 Not available ( <sub>3</sub> )
- 31.**

*\*If positive LKM1 value, complete either a or b depending on laboratory results:*

**a. Titer (record only the denominator):**

1/ \_\_\_\_\_

**b. Units:** \_\_\_\_\_ • \_\_\_\_\_

**31. Rheumatoid factor (RF):**

- Positive ( \*<sub>1</sub> )  
 Negative ( <sub>2</sub> )  
 Not available ( <sub>3</sub> )
- 32.**

*\*If positive, record RF value.*

**a. Units:** \_\_\_\_\_ • \_\_\_\_\_  
 IU/mL

*If results are given as a titer, record as "n" and key the actual result in the General Comments.*

**H. Immunoglobulin levels**

**32. Are immunoglobulin levels available:**

- ( Yes ( <sub>1</sub> ) ) ( No ( <sub>2</sub> ) )
- 37.**

**33. Date of blood draw for immunoglobulin levels:**

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

**34. IgA:** \_\_\_\_\_ mg/dL

**35. IgG:** \_\_\_\_\_ mg/dL

**36. IgM:** \_\_\_\_\_ mg/dL

**I. Other screening blood tests**

**37. Date of blood draw for thyroid stimulating hormone (TSH)\*:**

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Repeat if date is greater than 5 years prior to screening. \*Optional if patient under age 18; enter "m" if not done.*

**38. Thyroid stimulating hormone:**

\_\_\_\_\_ • \_\_\_\_\_  
 μU/mL

**J. Administrative information**

**39. Study Physician PIN:** \_\_\_\_\_

**40. Study Physician signature:**  
 \_\_\_\_\_

**41. Clinical Coordinator PIN:** \_\_\_\_\_

**42. Clinical Coordinator signature:**  
 \_\_\_\_\_

**43. Date form reviewed:**

\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year



**e. Hepatitis C virus RNA:**

Positive

( 1 )

Negative

( 2 )

Not available

( 3 )

**f. Hepatitis A virus antibody  
(anti-HAV, total):**

Positive

( 1 )

Negative

( 2 )

Not available

( 3 )

**C. Iron**

**11. Date of blood draw for iron overload screening:**

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

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

**a. Iron:**

\_\_\_\_ μg/dL

**b. Total iron binding capacity:**

\_\_\_\_ μg/dL

**c. Ferritin:**

\_\_\_\_ ng/mL

**12. Is hepatic iron index available:**

( Yes ) ( No )  
( 1 ) ( 2 )  
**14.**

**13. Hepatic iron index:**

\_\_\_\_ μMoI/g/year

**D. HFE gene analysis**

**14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:**

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

**17.**

**15. Date of blood draw for HFE gene analysis:**

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

**16. Type of abnormality (WT = wild type; check only one):**

- None ( 0 )
- C282Y/H63D heterozygote mutation ( 1 )
- C282Y/C282Y homozygote mutation ( 2 )
- C282Y/WT heterozygote mutation ( 3 )
- H63D/WT heterozygote mutation ( 4 )
- H63D/H63D homozygote mutation ( 5 )

**E. Ceruloplasmin**

**17. Is patient 40 years old or younger:**

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

**18.**

**a. Is a ceruloplasmin value available:**

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

**20.**

**18. Date of blood draw for ceruloplasmin: (required only if patient is 40 years old or younger; record if available if patient is greater than 40 years old):**

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
day mon year

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

**19. Ceruloplasmin**

\_\_\_\_ mg/dL

**a. Upper limit of normal:**

\_\_\_\_ mg/dL

**b. Lower limit of normal:**

\_\_\_\_ mg/dL



**F. Alpha-1 antitrypsin**

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

\_\_\_\_ day - \_\_\_\_ mon - \_\_\_\_ year

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

21. Alpha-1 antitrypsin (A1AT) \_\_\_\_\_ mg/dL

a. Upper limit of normal: \_\_\_\_\_ mg/dL

b. Lower limit of normal: \_\_\_\_\_ mg/dL

22. A1AT phenotype\* (check only one):

- MM ( 1 )
- MS ( 2 )
- MZ ( 3 )
- SZ ( 4 )
- ZZ ( 5 )
- Other (specify): ( 6 )

\_\_\_\_\_ specify  
Not available ( 7 )

\*If the phenotype result includes numbers, the numbers should be disregarded when reporting the result (e.g., M1M2 should be reported as MM).

23. Is A1AT deficiency the primary cause of this patient's liver disease (physician assessment):

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

**Eng**

**G. Autoantibody studies**

24. Date of blood draw for autoantibody tests:

\_\_\_\_ day - \_\_\_\_ mon - \_\_\_\_ year

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

25. Antinuclear antibody (ANA):

- Positive ( \* 1 )
- Negative ( 2 )

**26.** \_\_\_\_\_

\*If positive ANA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_ • \_\_\_\_\_

26. Antismooth muscle antibody (ASMA):

- Positive ( \* 1 )
- Negative ( 2 )

**27.** \_\_\_\_\_

\*If positive ASMA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_ • \_\_\_\_\_

27. Antimitochondrial antibody (AMA):

- Positive ( \* 1 )
- Negative ( 2 )

**28.** \_\_\_\_\_

Age < 18 and not done ( 3 )

**28.** \_\_\_\_\_

\*If positive AMA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/ \_\_\_\_\_

b. Units: \_\_\_\_\_ • \_\_\_\_\_

28. Is patient 18 or older:

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

**32.** \_\_\_\_\_

- 29. Lymphocytotoxic antibody (LCA):**  
 Positive ( \* )  
 Negative ( 2 )  
 Not available **30.**  ( 3 )  
**30.**

*\*If positive LCA value, complete either a or b depending on laboratory results:*

**a. Titer (record only the denominator):**  
 1/ \_\_\_\_\_

**b. Units:** \_\_\_\_\_ • \_\_\_\_\_

- 30. Antibody to liver-kidney microsomal antigen (LKM1):**  
 Positive ( \* )  
 Negative ( 2 )  
 Not available **31.**  ( 3 )  
**31.**

*\*If positive LKM1 value, complete either a or b depending on laboratory results:*

**a. Titer (record only the denominator):**  
 1/ \_\_\_\_\_

**b. Units:** \_\_\_\_\_ • \_\_\_\_\_

- 31. Rheumatoid factor (RF):**  
 Positive ( \* )  
 Negative ( 2 )  
 Not available **32.**  ( 3 )  
**32.**

*\*If positive, record RF value.*

**a. Units:** \_\_\_\_\_ • \_\_\_\_\_  
 IU/mL

*If results are given as a titer, record as "n" and key the actual result in the General Comments.*

**H. Immunoglobulin levels**

- 32. Are immunoglobulin levels available:**  
 ( Yes ) ( No )  
 ( 1 ) ( 2 )  
**37.**

**33. Date of blood draw for immunoglobulin levels:**  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

- 34. IgA:** \_\_\_\_\_ mg/dL  
**35. IgG:** \_\_\_\_\_ mg/dL  
**36. IgM:** \_\_\_\_\_ mg/dL

**I. Other screening blood tests**

**37. Date of blood draw for thyroid stimulating hormone (TSH)\*:**  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

*Repeat if date is greater than 5 years prior to screening. \*Optional if patient under age 18; enter "m" if not done.*

**38. Thyroid stimulating hormone:**  
 \_\_\_\_\_ • \_\_\_\_\_  
 μU/mL

**J. Administrative information**

**39. Study Physician PIN:** \_\_\_\_\_

**40. Study Physician signature:**  
 \_\_\_\_\_

**41. Clinical Coordinator PIN:** \_\_\_\_\_

**42. Clinical Coordinator signature:**  
 \_\_\_\_\_

**43. Date form reviewed:**  
 \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 day mon year

## NAFLD Database 2

## PE - Physical Examination

**Purpose:** Record physical exam findings of NAFLD Database 2 patients.

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

**Administered by:** Study Physician and Clinical Coordinator.

**Respondent:** Patient.

**Instructions:** Details of the protocol for height, weight, waist and hip measurement are found in the NAFLD Database 2 SOP I. In brief: height, weight, waist and hips should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Repeat waist measurements until you have two measurements within 4 inches (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 inches (10.2 cm) of each other.

### A. Center, patient, and visit identification

1. Center ID: \_\_\_\_\_

2. Patient ID: \_\_\_\_\_

3. Patient code: \_\_\_\_\_

4. Visit date: \_\_\_\_\_  
                   \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                   day                  mon                  year

5. Visit code: t \_\_\_\_\_

6. Form & revision: p e 1

7. Study: NAFLD Database 2 6

### B. Measurements

8. Height (*shoes off - repeat height measurements until you have two measurements within 0.5 inches (1.3 cm) of each other*):

a. 1st measurement: \_\_\_\_\_

b. 2nd measurement: \_\_\_\_\_

c. Units:  
 Inches ( 1 )  
 Centimeters ( 2 )

9. Weight (*shoes off - repeat weight measurements until you have two measurements within 2 lbs (0.91 kg) of each other*):

a. 1st measurement: \_\_\_\_\_

b. 2nd measurement: \_\_\_\_\_

c. Units:  
 Pounds ( 1 )  
 Kilograms ( 2 )

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

a. 1st measurement: \_\_\_\_\_

b. 2nd measurement: \_\_\_\_\_

c. Units:  
 Inches ( 1 )  
 Centimeters ( 2 )

11. Hip (*standing, at fullest part of the hips; repeat hip measurements until you have two measurements within 4 inches (10.2 cm) of each other*):

a. 1st measurement: \_\_\_\_\_

b. 2nd measurement: \_\_\_\_\_

c. Units:  
 Inches ( 1 )  
 Centimeters ( 2 )

12. Temperature (oral or other as appropriate for age):

- a. Degrees: \_\_\_\_\_ °
- b. Scale:
  - Fahrenheit: ( 1 )
  - Centigrade: ( 2 )

13. Blood pressure

- a. Systolic: \_\_\_\_\_ mmHg
- b. Diastolic: \_\_\_\_\_ mmHg

14. Resting radial pulse: \_\_\_\_\_ beats/minute

15. Respiratory rate: \_\_\_\_\_ breaths/minute

**C. Examination findings**

16. Areas with acanthosis nigricans (check all that apply):

- a. None: ( 1 )
- b. Neck: ( 1 )
- c. Axilla: ( 1 )
- d. Elbows: ( 1 )
- e. Knees: ( 1 )
- f. Knuckles: ( 1 )
- g. Periumbilical: ( 1 )

17. Abdomen abnormalities present (check all that apply):

- a. None: ( 1 )
- b. Ascites: ( 1 )
- c. Obese: ( 1 )
- d. Splenomegaly: ( 1 )
- e. Hepatomegaly: ( 1 )

If Yes, span at right midclavicular line:

\_\_\_\_\_ cm

**D. Liver signs**

18. Focused liver signs (check all that apply)

- a. None: ( 1 )
- b. Jaundice: ( 1 )
- c. Palmar erythema: ( 1 )
- d. Contractures: ( 1 )
- e. Pedal edema: ( 1 )
- f. Spider angiomata: ( 1 )
- g. Asterixis: ( 1 )
- h. Hepatic encephalopathy: ( 1 )
- i. Other, (specify): ( 1 )

\_\_\_\_\_ specify

**E. Tanner Staging**

19. Is Tanner staging required for this patient (Note: Required during screening if patient is 17 years old or younger.) (check only one):

- Yes, patient has not reached full sexual maturity and is 17 years old or younger: ( 1 )
- No, patient is 18 years old or older: ( 2 )

27. \_\_\_\_\_

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

( 3 )  
27. \_\_\_\_\_

20. Is the patient female:

- Yes ( 1 )
  - No ( 2 )
23. \_\_\_\_\_

**Male Tanner Staging**

21. Genital stage: \_\_\_\_\_  
1-5

22. Pubic hair stage: \_\_\_\_\_  
1-5

27. \_\_\_\_\_

**Female Tanner Staging**

23. Breast stage: \_\_\_\_\_  
1-5

24. Pubic hair stage: \_\_\_\_\_  
1-5

25. Has menarche occurred:  
( Yes )      ( No )  
  ( 1 )        ( 2 )  
                 **27.** ————

26. If yes, what was the patient's age at menarche:  
\_\_\_\_\_ \_\_\_\_\_  
age in years

**F. Administrative information**

27. Study Physician PIN: \_\_\_\_\_

28. Study Physician signature:  
\_\_\_\_\_

29. Clinical Coordinator PIN: \_\_\_\_\_

30. Clinical Coordinator signature:  
\_\_\_\_\_

31. Date form reviewed:  
\_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
          day                    mon                    year



**16.** Highest educational level achieved by patient (*show the patient/parent Flash Card #3 and ask the respondent to pick the category that describes the patient best; check only one*):

- Never attended school ( 0 )
- Kindergarten, pre kindergarten, or younger ( 1 )
- Grades 1 to 5 ( 2 )
- Grades 6-8 ( 3 )
- Grades 9-11 ( 4 )
- Completed high school ( 5 )
- Some college or post high school education or training ( 6 )
- Bachelor's degree or higher ( 7 )

**17.** Is the patient currently employed:

Yes ( 1 )      No ( 2 )

**20.**

**18.** What is the patient's current occupation:

\_\_\_\_\_

specify occupation

**19.** About how many hours does the patient work each week: \_\_\_\_\_

# hours

**20.** Which of the following categories best characterizes the patient's occupational history (*show the patient/parent Flash Card #4 and ask the respondent to pick the category that describes the patient best; check only one*):

- Never employed ( 0 )
- Laborer ( 1 )
- Clerical ( 2 )
- Professional ( 3 )
- Homemaker ( 4 )
- Other, (*specify*): ( 5 )

\_\_\_\_\_

specify

**21.** Marital status of the patient (*show the patient/parent Flash Card #5 and ask the respondent to pick the category that describes the patient best; check only one*):

- Single, never married ( 1 )
- Married or living in marriage-like relationship ( 2 )
- Separated, divorced, or annulled ( 3 )
- Widowed ( 4 )

**22.** Combined annual income before taxes of all members of patient's household (*show the patient/parent Flash Card #6 and ask the respondent to pick the category that describes the patient's combined household income best; check only one*):

- Less than \$15,000 ( 1 )
- \$15,000 - \$29,999 ( 2 )
- \$30,000 - \$49,999 ( 3 )
- \$50,000 or more ( 4 )

**D. Previous registration in a NASH CRN study**

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

Yes ( 1 )      No ( 2 )

**27.**

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

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

\_\_\_\_\_

specify

**25.** ID Number previously assigned to patient (*record patient ID in item 2*): \_\_\_\_\_

**26.** Code previously assigned to patient (*record patient code in item 3*): \_\_\_\_\_

**28.**

**F. ID assignment**

*(If a STOP condition was checked in section B, the patient is ineligible and a Patient ID should not be assigned. If the patient was previously registered in a NASH CRN study, a new ID number should not be assigned.)*

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

CCCC      #####, zzz
----------------------

**G. Administrative information**

28. Clinical Coordinator PIN: \_\_\_\_ \_

29. Clinical Coordinator signature:  
\_\_\_\_\_

30. Date form reviewed:  
\_\_\_\_ \_ - \_\_\_\_ \_ - \_\_\_\_ \_  
day mon year