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. Ce	enter, patient, and vi	sit identification	l	(7	Iministrative information To be completed by Clinical Coordi	inator after	
1.	Center ID:			Si	urvey is completed.)		
2.	Patient ID:			8.	How was the questionnaire comp	oleted:	
3.	Patient code:				Self-administered by patient Interview with translator	(1) 2)
4.	Date of visit (date p	atient completed	the form):				
				9.	Clinical Coordinator		
	day	mon	year		a. PIN:b. Signature:		_
5.	Visit code:	<u>t</u> _0_			b. Signature.		
6.	Form & revision:	<u>a</u> .	<u>d</u> 1	10.	Date form reviewed:		
7.	Study:	NAFLD Da	tabase 2 <u>6</u>		_	_	
					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
	(1)	(2)	(3)	(4)

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

1 or 2	3 or 4	5 or 6	7 to 9	10 or more
(0)	(1)	(2)	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(4)

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

Less than				Daily or
Never	monthly	Monthly	Weekly	almost daily
()	(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?

Less than				Daily or
Never	monthly	Monthly	Weekly	almost daily
$\begin{pmatrix} 0 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 4 \end{pmatrix}$

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

Less than				Daily or	
Never	monthly	Monthly	Weekly	almost daily	
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(1)	(2)	(3)	(4)	

Patient ID:		

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?

Less than			Daily or	
Never	monthly	Monthly	Weekly	almost daily
(0)	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(3)	(4)

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

Less than				Daily or
Never	monthly	Monthly	Weekly	almost daily
$\begin{pmatrix} 0 \end{pmatrix}$	$\begin{pmatrix} & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(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?

	Less than			Daily or
Never	monthly	Monthly	Weekly	almost daily
()	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(3)	$\begin{pmatrix} & & & \\ & & & \end{pmatrix}$

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

	Yes, but not in	Yes, during
No	the last year	the last year
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

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

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

21. Today's date:

Thank you for completing this questionnaire.

NAFLD Database 2

BG - Baseline History

Purpose : To collect baseline history information about the p When : Visit t0.	patient.		
Administered by: Clinical Coordinator, reviewed by Study	Physician.		
Respondent : Patient or patient's parent.			
Instructions : Collect information by interview and chart revagrees with the diagnosis, the patient is ineligible for the Market patient is ineligible and cannot enroll in the NAFLD Description of the state of th	NAFLD Database 2 Study. If 🕪 is checked for Database 2 Study. The form should not be keyed	an ite to th	e
data system; but the form should be set aside with forms f to be ineligible.	of other patients who started screening, but were	Ioun	.u
A. Center, visit, and patient identification	9. If yes, characterize the liver disease(s) <i>(check all that apply)</i>		
1. Center ID:	a. Alcohol related liver disease:	(1)
2. Patient ID:	b. Viral hepatitis:	(1)
2. Patient ID	c. Alpha-1 antitrypsin deficiency:	(1)
3. Patient code:	d. Wilson's disease:	(1)
	e. Glycogen storage disease:	(1)
4. Visit date (date this form is initiated):	f. Iron overload:	(1)
day mon year	g. Fatty liver disease (NAFLD, NASH):	(1)
	h. Type of liver disease unknown:	(1)
5. Visit code:t0	i. Other (specify):	(1)
6. Form & revision:bg1			12
	specify		
7. Study: NAFLD Database 2 6	10. Do any of the patient's first degree		
B. Family history	relatives (parent, brother, sister, child) have cirrhosis:		
9. De anno Cilla matical de Contabrance	Yes	N	4o /
8. Do any of the patient's first degree relatives (parent, brother, sister, child) have liver disease:	(₁)	<u>2.</u> —	₂)
$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$	11. If yes, is the cause of the cirrhosis		
10	NASH-related or unknown (cryptogenic)		
[=vv.]	$\binom{\mathrm{Yes}}{1}$	(2)
	12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2):		
	Yes	(1)
	No	(2)
	Don't know	(3)
	13. Do any of the patient's first degree relatives (parent, brother, sister, child) have obesity:		
	Yes	(1)
	No	(2
	Don't know	((د

14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat: Yes	(1)	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
No	(2)	Biopsy Materials Documentation (SD) forms for
Don't know	(3)	this biopsy):
15. Do any of the patient's first degree relatives (parent, brother, sister, child) have a problem with cholesterol or blood fat:	d		*Blood drawn for specimen collection must be within 90 days of the biopsy.
Yes	(1)	7 7 1 7
No	Ì	2)	20. Date of liver biopsy no more than 90
Don't know	(3)	days prior to registration in Database 2 Study that you want evaluated:
C. NAFLD history			
16. Date patient was first diagnosed with fatty liver disease or NASH-related			day mon year 21. Will the patient have a biopsy during
cirrhosis:			screening:
day mon	year		$\binom{\text{Yes}}{*}_{1}$ $\binom{\text{No}}{2}$
17. What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis <i>(check all that apply)</i>			*Complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy. Blood draw for banking should be done <u>prior</u> to the biopsy or 4 days
a. Symptoms for liver disease:	(1)	<u>after</u> the biopsy.
b. Result of being evaluated for another illness:	. (1)	22. Has the patient had a liver imaging study in the past 6 months:
c. During a routine or insurance physica examination:	ıl (1)	
d. Blood donation:	Ò	1)	*Complete the Liver Imaging Studies Report (IR)
e. Other (specify):	(1)	form.
(1 33)		12	D. Weight history
specify			23. What was the patient's birthweight:
18. What procedures/tests supported this fire diagnosis <i>(check all that apply)</i>	st		lbs oz
a. Liver biopsy:	(1)	24. Review flashcard 11. Which (picture)
b. Imaging studies (Ultrasound, CT, MI	RI): (1)	best describes your weight pattern over the past 5 years (check only one):
c. Elevated aminotransferases:	(1)	
d. Other (specify):	(1)	Up and down, up and down (1)
			Up gradually (2) Up sharply (agined a lot in a brief interval) (2)
specify			Up sharply (gained a lot in a brief interval) (3)
			Down gradually 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

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

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

Gain weight Lose weight

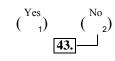
36. Which did the patient try to do (check only one):

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

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

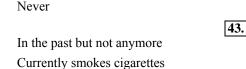
37. Is the patient age 12 or older:

age in years



28. Is the patient age 18 or older:

38. Have you ever smoked tobacco cigarettes:



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

30. At what age did the patient weigh the

least since age 18:

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):

age in years

lbs

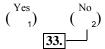
lbs

Y	es	N	lо
(1)	(2)
	4	13. —	J

years

years

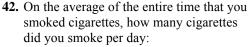
- 31. Does the patient weigh more than he/she did one year ago:
- 40. How old were you when you first started regular cigarette smoking:

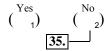


32. How much more does the patient weigh now compared to one year ago:

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

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





lbs

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

cigarettes/day

F. Menstrual history

43. Is the patient female:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(₂)
	49.

44. Has menarche occurred:

Yes ((No
()	49.

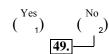
45. If yes, what was the patient's age at menarche:

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	(()

47. Is patient post-menopausal:



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:
 - **b.** Diabetes type 2:
 - **c.** Gestational diabetes (diabetes of pregnancy):
 - d. Hepatitis B:
 - e. Hepatitis C:

f.	Autoimmune hepatitis:	(1)
	rate illiniane nepatitis.	(- 1	١.

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

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

 $\binom{No}{2}$

	af. Seizure disorder or epilepsy:	(1)	51. Organ, limb, or bone marrow transplant
	ag. Drug allergies:	(1)	a. Has the patient ever received a liver
	ah. Hypothyroidism:	(1)	transplant: Yes
	ai. Hypertension:	(1)	(1)
	aj. Cerebrovascular disease:	(1)	b. Has the patient ever received any other organ, limb, or bone marrow
	ak. Dysbetalipoproteinemia:	_ (1)	transplant:
		C/-	_	$\begin{pmatrix} \text{Yes} \\ \binom{1}{1} \end{pmatrix}$
	al. Chronic cholestasis:	(1)	52 H. d.
	am. Hyperlipidemia (high cholesterol, high triglycerides):	()	52. Has the patient received total parenteral nutrition (TPN) for more than 1 month
	an. Pancreatitis:	(1) 1)	within 6 months prior to liver biopsy:
	ao. Cholelithiasis:	(1)	$\binom{\text{Yes}}{1}$
	ap. Coronary artery disease:	(1)	<u> </u>
	aq. Elevated uric acid such as gout:	(1)	53. Is the patient currently undergoing
	ar. Kidney disease:	(1)	evaluation for bariatric surgery:
	as. Polycystic ovary syndrome:	(1)	$\binom{\text{Yes}}{1}$
	at. Sleep apnea (not breathing during sleep):	(1)	54. Does the patient have symptoms
	au. Dermatologic disorders:	(1)	suggestive of sleep apnea (snoring, observed periods of apnea, disruptive
	av. Myopathy:	(1)	sleep disturbances):
	aw. Myositis:	(1)	$\binom{\text{Yes}}{1}$
	ax. Major depression:	(1)	
	ay. Schizophrenia:	(1)	
	az. Bipolar disorder:	(1)	
	ba. Obsessive compulsive disorder:	(1)	
	bb. Severe anxiety or personality disorder:	(1)	
	bc. None of the above:	(1)	
50.	Has the patient ever had surgery for any of the following (check all that apply)			
	a. Stapling or banding of the stomach:	<u>(</u>	₁)	
	b. Jejunoileal <i>(or other intestinal)</i> bypas prior to the diagnosis of NAFLD:	c\(₁)	
	c. Biliopancreatic diversion:	\overline{c}	₁)	
	d. Other GI or bariatric surgery (specify,): (1)	

e. None of the above:

H. Medication use

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

(₁)	(2)
56	.]—	J
(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)
1. Repaglinide (Prandin):	(1)

Yes

No

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

Yes	No)
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
	57.	

1)

1)

1)

(If yes, check all that apply):

m. Rosiglitazone (Avandia):

n. Tolazamide (Tolinase):

o. Tolbutamide (Orinase):

p. Other, (specify):

a.	a. Chlordiazepoxide (Librium):			
b.	Clorazepate dipotassium (Tranxene):	(1	

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

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
, 17	[50] [
	58.

(If yes, check all that apply):

a. Atorvastatin (Lipitor):	(1)
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Y	es	N	lo
(1)	(2)
	1	59. —	J

(If yes, check all that apply):

1)

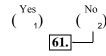
59. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 3 months:

$\binom{\text{Yes}}{1}$	(No 2)
	60.

1)

(If yes, check all that apply):

- **a.** Acetaminophen (Tylenol):
- **b.** Aspirin 325 mg: (
- **c.** Aspirin 81 mg: (₁)
- **d.** Celecoxib (Celebrex):
- e. Ibuprofen (Advil, Motrin):
- **f.** Indomethacin (Indocin):
- **g.** Naproxen (Aleve, Naprosyn):
- **h.** Rofecoxib (Vioxx):
- **i.** Other, (specify):
- **j.** Other, (specify): $\begin{pmatrix} 1 \end{pmatrix}$
- **60.** Has the patient taken any strong opiates containing acetaminophen medication in the past 3 months:



(If yes, check all that apply):

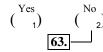
- **a.** Darvocet:
- **b.** Esgic Plus: (1)
- **c.** Fioricet:
- **d.** Lorcet:
- e. Lortab:
- **f.** Norco:
- g. Percocet:
- **h.** Talacen:
- **i.** Tylenol #3: (1)
- **j.** Tylenol #4: (1)
- **k.** Tylox: (₁)
- **1.** Vicodin: (1)
- **m.** Wygesic:
- **n.** Other, (specify):

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

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
	62.

(If yes, check all that apply):

- **a.** Cimetidine (Tagamet):
- **b.** Esomeprazole magnesium (Nexium):
- c. Famotidine (Pepcid):
- **d.** Lansoprazole (Prevacid):
- e. Nizatidine (Axid):
- **f.** Omeprazole (Prilosec):
- g. Ranitidine (Zantac):
- **h.** Ranitidine bismuth citrate (Tritec): (1)
- i. Antacids, (specify):
- **j.** Other, (specify):
- **62.** Has the patient taken any anticoagulant/antiplatelet medications in the past 3 months:



(If yes, check all that apply):

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

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

g. Prednisolone (Prelone):

Aristocort, Kenacort):

i. Triamcinolone (Acetocot, Amcort,

h. Prednisone:

j. Other, (specify):

$\binom{\operatorname{Yes}}{1}$	(N	√o 2)
(If yes, check all that apply):	4.	J
a. Betamethasone sodium (Celestone):	(1)
b. Cortisol:	(1)
c. Cortisone:	(1)
d. Dexamethasone (Decadron):	(1)
e. Hydrocortisone (Hydrocortone):	(1)
f. Methylprednisolone (Solu-Medrol):	(1)

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

Y	es		N	lо
(1)		(2
		65.		_

(If yes, check all that apply):

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

1)

1)

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):
- e. Ethinyl estradiol (Estinyl):
- **f.** Fluoxymesterone (Android-F, Halotestin):
- **g.** Levonorgestrel (Norplant): (1)
- **h.** Medroxyprogesterone (Cycrin, Provera): (1)
- i. Megestrol (Megace):
- **j.** Methyltestosterone (Android): (1)
- **k.** Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin): (,)
- **l.** Norethindrone (Micronor):
- m. Norgestrel (Ovrette):
- **n.** Oral contraceptives: (1)
- o. Oxandrolone (Oxandrin):
- **p.** Oxymetholone (Anadrol):
- **q.** Progesterone (Prometrium):
- r. Raloxifene (Evista):
- s. Tamoxifen (Nolvadex):
- s. Tamoxiten (Nolvadex):
- **t.** Other, (specify): $\begin{pmatrix} 1 \end{pmatrix}$

u.	Other, (specify):	(

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

$\binom{\text{Yes}}{1}$	$\binom{\text{No}}{2}$
	67.

(If yes, check all that apply):

- a. Beclomethasone dipropionate (Beclovent, Vanceril):
- **b.** Budesonide (Pulmicort, Rhinocort): (1)
- **c.** Fluticasone propionate (Flonase, Flovent):
- **d.** Loratadine (Claritin):
- e. Mometasone furoate (Nasonex):
- **f.** Triamcinolone acetonide (Azmacort, Nasacort): (1)
- **g.** Other, (specify):
- **h.** Other, (specify):
- **67.** Has the patient taken a multivitamin regularly in the past 3 months:

Y	es	N	Ю
(1)	(2)

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

Ye	S (1	No (
(1)	(2
	7	'0. —	J

- **69.** Which vitamins has the patient taken *(check all that apply)*:
 - **a.** Vitamin B (any type): (1) **b.** Vitamin C: (4)
 - 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)	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 + betain adenosine + pyridoxine (Epocl		(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. Garlie:		(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)

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

$\binom{\text{Yes}}{1}$	$\binom{No}{2}$
	72.

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

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

ad. Other, (specify):

Patient ID:	 	

T 4	١dm	ninic	trativ	e infa	rmation

72.	Study Physician PIN:	 	
73.	Study Physician signature:		
74.	Clinical Coordinator PIN:	 	
75.	Clinical Coordinator signature:		
76.	Date form reviewed:):	 	
	day mon	ye	ar

NAFLD Database 2

BG - Baseline History

Purpose : To collect baseline history information about the	nationt		
When: Visit t0.	patient.		
Administered by: Clinical Coordinator, reviewed by Study	Physician.		
Respondent : Patient or patient's parent. Instructions : Collect information by interview and chart review.	view. If (s) is checked for an item, and the physic	ician	
agrees with the diagnosis, the patient is ineligible for the the patient is ineligible and cannot enroll in the NAFLD I	NAFLD Database 2 Study. If 🕬 is checked for Database 2 Study. The form should not be keyed	an ite to th	em, ne
data system; but the form should be set aside with forms to be ineligible.	for other patients who started screening, but were	four	nd
A. Center, visit, and patient identification	9. If yes, characterize the liver disease(s) (check all that apply)		
1. Center ID:	a. Alcohol related liver disease:	(1)
2. Patient ID:	b. Viral hepatitis:	(1)
2. I diferit 1D	c. Alpha-1 antitrypsin deficiency:	(1)
3. Patient code:	d. Wilson's disease:	(1)
	e. Glycogen storage disease:	(1)
4. Visit date (date this form is initiated):	f. Iron overload:	(1)
day mon year	g. Fatty liver disease (NAFLD, NASH):	(1)
	h. Type of liver disease unknown:	(1)
5. Visit code:t0	i. Other (specify):	(1)
6. Form & revision:bg2			
	specify		
7. Study: NAFLD Database 2 6	10 D./II		
B. Family history	10. Do/did any of the patient's first degree relatives (parent, brother, sister, child) have cirrhosis:		
8. Do/did any of the patient's first degree	Yes (Yes	(No \
relatives (parent, brother, sister, child) have liver disease:	<u> </u>	2.]—	
$\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$	11. If yes, is the cause of the cirrhosis NASH-related or unknown (cryptogenic)		
Did any of the national's first degree	Yes (1)		No 、
a. Did any of the patient's first degree relatives die from liver disease:	(1)	(2)
$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$	12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2):		
	Yes	((ر
	No	(2)
	Don't know	(3)
	13. Do any of the patient's first degree relatives (parent, brother, sister, child) have obesity:		
	Yes	(1)
	No	(2)
	Don't know	(3)

Patient		

14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat: Yes No	(1) 2)	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):
Don't know	(3)	$\begin{pmatrix} \text{Yes} & \text{No} \\ * & 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ & 2 \end{pmatrix}$
15. Do any of the patient's first degree relatives (parent, brother, sister, child) have a problem with cholesterol or blood fat:	d		*Blood drawn for specimen collection must be within 90 days of the biopsy.
Yes	(1)	
No	(2)	20. Date of liver biopsy no more than 90
Don't know	(3)	days prior to registration in Database 2 Study that you want evaluated:
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:
day mon	year		$\binom{\text{Yes}}{*}$ $\binom{\text{No}}{2}$
17. What prompted the evaluation for NAFLD, NASH, or NASH-related cirrhosis (check all that apply)			*Complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy. Blood draw for banking should be done <u>prior</u> to the biopsy or 4 days
a. Symptoms for liver disease:	(1)	<u>after</u> the biopsy.
b. Result of being evaluated for another illness:	. (1)	22. Has the patient had a liver imaging study in the past 6 months:
c. During a routine or insurance physica examination:	ıl (1)	$\binom{\text{Yes}}{*}_{1} \qquad \binom{\text{No}}{2}$
d. Blood donation:	(1)	*Complete the Liver Imaging Studies Report (IR)
e. Other (specify):	(1)	form.
	Ì	.,	D. Weight history
specify			23. What was the patient's birthweight:
18. What procedures/tests supported this first diagnosis <i>(check all that apply)</i>	st		lbs oz
a. Liver biopsy:	(1)	24. Review flashcard 11. Which (picture)
b. Imaging studies (Ultrasound, CT, MI	RI): (1)	best describes your weight pattern over the past 5 years (check only one):
c. Elevated aminotransferases:	(1)	
d. Other (specify):	(1)	Up and down, up and down $\begin{pmatrix} 1 \end{pmatrix}$ Up gradually $\begin{pmatrix} 2 \end{pmatrix}$
			Up sharply (gained a lot in a brief interval) (3)
specify			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

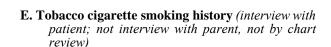
35. Did the patient try to lose or gain weight:

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

Gain weight	(1)
Lose weight	((ا

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

27. At what age did the patient weigh the

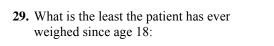


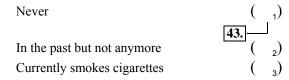
most:



$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

28. Is the patient age 18 or older:





- **30.** At what age did the patient weigh the least since age 18:
- **39.** Did you smoke cigarettes regularly ("No" means less than 20 packs of cigarettes in a lifetime or less than I cigarette a day for one year):



lbs

lbs

age in years

years

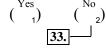
31. Does the patient weigh more than he/she did one year ago:

32. How much more does the patient weigh

now compared to one year ago:

did one year ago:

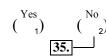
40. How old were you when you first started regular cigarette smoking:



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:

tient	weigh	

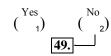
cigarettes/day

F. Menstrual history

43. Is the patient female:

Yes (Yes	(No
()	49.

44. Has menarche occurred:



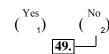
45. If yes, what was the patient's age at menarche:

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:



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:
 - **b.** Diabetes type 2: $\binom{1}{1}$
 - **c.** Gestational diabetes (diabetes of pregnancy):
 - d. Hepatitis B:
 - e. Hepatitis C:

f.	Autoimmune hepatitis:	(1)
••	ratommane nepatitis.	(1

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



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

j. Glycogen storage disease:	(₁)
	(C\-

k. Iron overload:

1 D 1 (' 1' 1'	1	`
l. Polycystic liver disease:	(1/

q. Other gastrointestinal bleeding:
$$\binom{1}{1}$$

y. Hemophilia (bleeding disorder):

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

ab. Endocrine disease (hormonal abnormality):

ac. Hepatocellular carcinoma:

ad. Other malignancy (cancer):

ae. Peripheral neuropathy: (1)

 $\binom{No}{2}$

	af. Seizure disorder or epilepsy:	(1)	51. Organ, limb, or bone marrow transplant
	ag. Drug allergies:	(1)	a. Has the patient ever received a liver
	ah. Hypothyroidism:	(1)	transplant: Yes
	ai. Hypertension:	(1)	(1)
	aj. Cerebrovascular disease:	(1)	b. Has the patient ever received any other organ, limb, or bone marrow
	ak. Dysbetalipoproteinemia:	(1)	transplant:
		<u>c/</u> —		Yes (1)
	al. Chronic cholestasis:	(1)	
	am. Hyperlipidemia (high cholesterol, high triglycerides):	(1)	52. Has the patient received total parenteral nutrition (TPN) for more than 1 month within 6 months prior to liver biopsy:
	an. Pancreatitis:	(1)	Yes
	ao. Cholelithiasis:	(1)	(1)E
	ap. Coronary artery disease:	(1)	Y
	aq. Elevated uric acid such as gout:	(1)	53. Is the patient currently undergoing
	ar. Kidney disease:	(1)	evaluation for bariatric surgery: Yes
	as. Polycystic ovary syndrome:	(1)	$\binom{1}{1}$
	at. Sleep apnea (not breathing during sleep):	(1)	54. Does the patient have symptoms suggestive of sleep apnea <i>(snoring,</i>
	au. Dermatologic disorders:	(1)	observed periods of apnea, disruptive
	av. Myopathy:	(1)	sleep disturbances): Yes
	aw. Myositis:	(1)	(1)
	ax. Major depression:	(1)	
	ay. Schizophrenia:	(1)	
	az. Bipolar disorder:	(1)	
	ba. Obsessive compulsive disorder:	(1)	
	bb. Severe anxiety or personality disorder:	(1)	
	bc. None of the above:	(1)	
50.	Has the patient ever had surgery for any of the following (check all that apply)			
	a. Stapling or banding of the stomach:	<u>(</u>	(_L	
	b. Jejunoileal (or other intestinal) bypas prior to the diagnosis of NAFLD:	s (<u>C</u>	1)	
	c. Biliopancreatic diversion:	<u>(</u>	1)	
	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:

$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	(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)

Yes

No

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

Yes	No
((,)
(1)	
	57.

1)

1)

1)

(If yes, check all that apply):

n. Tolazamide (Tolinase):

o. Tolbutamide (Orinase):

p. Other, (specify):

a.	Chlordiazepoxide (Librium):	(1)	
b.	Clorazepate dipotassium (Tranxene):	(1)	

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

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	58.

(If yes, check all that apply):

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

Y	es		N	0
(1)	(2)
		59. –		

(If yes, check all that apply):

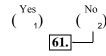
1)

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

Yes	, 1	(No 2
	6	0.	

(If yes, check all that apply):

- **a.** Acetaminophen (Tylenol):
- **b.** Aspirin 325 mg: (
- **c.** Aspirin 81 mg:
- **d.** Celecoxib (Celebrex):
- e. Ibuprofen (Advil, Motrin):
- to touploid (ruyii, riouiii).
- **f.** Indomethacin (Indocin):
- **g.** Naproxen (Aleve, Naprosyn): (
- **h.** Rofecoxib (Vioxx):
- **i.** Other, (specify):
- **j.** Other, (specify): $\begin{pmatrix} 1 \end{pmatrix}$
- **60.** Has the patient taken any strong opiates containing acetaminophen medication in the past 3 months:



(If yes, check all that apply):

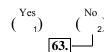
- **a.** Darvocet:
- **b.** Esgic Plus: (1)
- **c.** Fioricet: (1)
- **d.** Lorcet: (1
- e. Lortab:
- **f.** Norco:
- g. Percocet:
- **h.** Talacen:
- **i.** Tylenol #3: (1)
- **j.** Tylenol #4: (1)
- **k.** Tylox: (₁)
- **1.** Vicodin: (1)
- **m.** Wygesic:
- **n.** Other, (specify):

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

$\binom{\text{Yes}}{1}$	$\binom{No}{2}$
	62.

(If yes, check all that apply):

- **a.** Cimetidine (Tagamet):
- **b.** Esomeprazole magnesium (Nexium):
- c. Famotidine (Pepcid):
- **d.** Lansoprazole (Prevacid):
- e. Nizatidine (Axid):
- **f.** Omeprazole (Prilosec):
- g. Ranitidine (Zantac):
- **h.** Ranitidine bismuth citrate (Tritec): (1)
- i. Antacids, (specify):
- **j.** Other, (specify):
- **62.** Has the patient taken any anticoagulant/antiplatelet medications in the past 3 months:



(If yes, check all that apply):

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

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

(Yes 1	(N	lo 2)
	64]—	J
(If yes, check all that apply):			
a. Betamethasone sodium (Celes	stone):	(1
b. Cortisol:		(1)
c. Cortisone:		(1)
d. Dexamethasone (Decadron):		(1)
e. Hydrocortisone (Hydrocorton	e):	(

- e. Hydrocortisone (Hydrocortone): (
- **f.** Methylprednisolone (Solu-Medrol): (
- g. Prednisolone (Prelone): (1)
 h. Prednisone: (2)
- i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort):
- **j.** Other, (specify): (

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

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	65.

(If yes, check all that apply):

- **a.** Amiodarone (Pacerone):
- **b.** Amlodipine besylate (Norvasc):
- **c.** Atenolol (Tenormin):
- **d.** Benazepril (Lotensin):
- e. Captopril (Capoten):
- **f.** Clonidine (Catapres):
- g. Digoxin (Lanoxin):
- **h.** Diltiazem (Cardizem):
- i. Doxazosin (Cardura):
- **j.** Enalapril (Vasotec):
- k. Felodipine (Plendil):
- **l.** Furosemide (Lasix):
- **m.** Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)
- **n.** Hydrochlorothiazide + triamterene (Dyazide): (1)
- o. Lisinopril (Prinivil, Zestril):
- **p.** Losartan potassium (Cozaar):
- **q.** Losartan potassium with hydrochlorothiazide (Hyzaar): (1)
- **r.** Metoprolol (Lopressor):
- s. Nifedipine (Adalat, Procardia):
- **t.** Perhexiline maleate: (1)
- u. Propranolol (Inderal):
- v. Quinapril (Accupril):
- **w.** Terazosin (Hytrin):
- **x.** Timolol maleate (Blocadren):
- y. Valsartan (Diovan):
- **z.** Verapamil (Calan): (1)
- **aa.** Other, (specify):
- **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):
- **c.** Esterified estrogen (Estratab, Menest):
- 1) **d.** Estradiol (Estrace):
- e. Ethinyl estradiol (Estinyl):
- **f.** Fluoxymesterone (Android-F, Halotestin):
- g. Levonorgestrel (Norplant): 1)
- h. Medroxyprogesterone (Cycrin, 1) Provera):
- 1) i. Megestrol (Megace):
- **j.** Methyltestosterone (Android): 1)
- k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin): 1)
- **1.** Norethindrone (Micronor): 1)
- 1) **m.** Norgestrel (Ovrette):
- 1) **n.** Oral contraceptives:
- o. Oxandrolone (Oxandrin): 1)
- **p.** Oxymetholone (Anadrol): 1)
- **q.** Progesterone (Prometrium): 1)
- 1) **r.** Raloxifene (Evista):
- 1) s. Tamoxifen (Nolvadex):
- 1)
- **t.** Other, (specify):
- 1) **u.** Other, (specify):

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

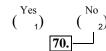
Yes (1)	$\binom{\text{No}}{2}$
·	67.

(If yes, check all that apply):

- a. Beclomethasone dipropionate (Beclovent, Vanceril): 1)
- **b.** Budesonide (Pulmicort, Rhinocort):
- c. Fluticasone propionate (Flonase, Flovent):
- **d.** Loratadine (Claritin):
- **e.** Mometasone furoate (Nasonex):
- f. Triamcinolone acetonide (Azmacort, Nasacort): 1)
- g. Other, (specify):
- **h.** Other, (specify):
- 67. Has the patient taken a multivitamin regularly in the past 3 months:

Y	es	N	Ю
(1)	(2)

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



- **69.** Which vitamins has the patient taken (check all that apply):
 - a. Vitamin B (any type): **b.** Vitamin C:
 - c. Vitamin D: **d.** Vitamin E:
 - e. Other, (specify):

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

Yes	No	,
(1)	71.	2)
(If yes, check all that apply):	/1.	
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)
ah. Zinc picolinate:	(.)

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

Yes	(No)
\ I/	72.	′

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

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

ac. Other, (specify):

ad. Other, (specify):

Patient			
rauciii	 -	-	-

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	C. Administrative information		
1.	1. Center ID:			(To be completed by clinical center staff after surve is completed.)	
2.	Patient ID:			24. Clinical Coordinator PIN:	
3.	Patient code:			25. Clinical Coordinator signature:	
4.	Date of visit :				
	 day	 	year	26. Date form reviewed:	
5.	Visit code:	t		day mon year	
6.	Form & revision:	<u>b</u>	<u>q</u> 1		
7.	Study:	NAFLD Dat	tabase 2 <u>6</u>		

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".

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

,) Do not cour	nt beverages	used in cook	ing or other	preparations	such as i	milk in c	ereal.
٠.	, Do not cour	it be verages	useu III coor	ing or ource	preparations	, such as i		Cicai.

4) Count milk added to tea	and coffee in the tea/coffee wi	th cream beverage categor	NOT in the milk categories.
----------------------------	---------------------------------	---------------------------	------------------------------------

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

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

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Affix label here

Patient ID:
Patient code:
Visit code:

CG - Genetic Consent and Blood Collection Documentation NAFLD Database 2

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

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 Reposi-

tory.					
A. Center, patient a	nd visit id	entifi	cation	ı	
1. Center ID:					
2. Patient ID:					
3. Patient code:					
4. Date form comp	oleted:				
day		mon	=	ye	
5. Visit code:					
6. Form & revision	ı:		<u>_c</u> _	_g_	_1_
7. Study:	NAFLE) Dat	abase	e 2	_6_
B. Consent for colle- samples for curre		-			

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

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

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

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

Y	es .	N	o
(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:

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:

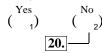
$$\binom{\mathrm{Yes}}{1}$$
 $\binom{\mathrm{No}}{2}$

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

year

14. In your judgment, has the patient/parent consented to collection of blood for DNA

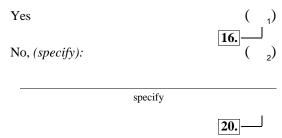
banking (this question is asked in recognition that not all IRBs will have approved consent statements that include language that can be mapped into the questions in items 10 through 12; a response of "No" to this question (item 14) means that blood should NOT be collected for sending to the Genetics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



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:



- 16. Date and time of blood draw
- **17.** Number of 10 mL EDTA tubes:
- **18.** Form copy of tube labels:

19. Phlebotomist:

pri	int name	

- **20.** Study Physician PIN:
- 21. Study Physician signature:
- 22. Clinical Coordinator PIN:
- **23.** Clinical Coordinator signature:
- **24.** Date form reviewed:

day

mon

CG - Genetic Consent and Blood Collection Documentation NAFLD Database 2

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

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 Reposi-

tory.					
A. Center, patient a	and visit id	lentific	ation	1	
1. Center ID:					
2. Patient ID:					
3. Patient code:					
4. Date form comp	oleted:				
day	 =	mon		yea	ar
5. Visit code:					
6. Form & revision	n:		<u>c</u>	_g_	2
7. Study:	NAFLI	O Data	abase	e 2	6
B. Consent for colle samples for curr					
8. Has a sufficient micrograms) be Genetics Repos in a previous N.	en banked itory for th	at the is part	NIDE icipar		

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

specify

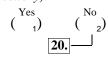
a. Database b. PIVENS c. TONIC

d. Other, (specify):

10. Does the patient/parent consent to genetic research on NAFLD or NASH-related cirrhosis that is currently planned by the study investigators: No 11. Does the patient/parent consent to future genetic research on NAFLD or NASH-related cirrhosis by this study or other study investigators: 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: 13. Other information related to consent for genetic research that clinic staff feel needs to be keyed to the study database (e.g., ifyour genetic consent had other options that are not covered by the 3 categories of use of samples specified above):

20.

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):



C. Specimen for Genetics Repository

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

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

Yes		(1
No, (specify):		16. (₂)
	specify	
		20.

- **16.** Date and time of blood draw
 - a. Date:

da		mon		year	
b. Time:		(.)	(,
hour	minute	- aı	m	pr	2/ n

- **17.** Number of 10 mL EDTA tubes:
- **18.** Form copy of tube label:

19. Phlebotomist:

- **20.** Study Physician PIN:
- **21.** Study Physician signature:
- 22. Clinical Coordinator PIN:
- **23.** Clinical Coordinator signature:
- 24. Date form reviewed:

 day mon year

Central Histology Review

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

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

By whom: Data Coordinating Center staff.

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

	A. Clinic, patient and visit identification 1. Center ID
	2. Patient ID
	3. Patient code
//	4. Date of central reading
	5. Visit code
<u>c r 2</u>	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. His H & E stain 13. Steatosis (assume macro, e.g., large and small drople a. Grade: 0 =<5%; 1 =5-33%; 2 =34-66%; 3 =>66%	tology t)

13.	Steatosis	(assume	macro,	e.g.,	large	and	small	drop	let)
-----	-----------	---------	--------	-------	-------	-----	-------	------	-----	---

_ ... 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

1 of 2

_ Patient ID	D. Histology (cont'a)
14. Inflammation	
	obular inflammation: combines mononuclear, fat granulomas, and pmn foci:
_	under 20x mag; 2 =2-4 under 20 mag; 3 =>4 under 20 mag
	omas seen: 0=No; 1=Yes
	anulomas seen: 0=No; 1=Yes
_	portal, chronic inflammation: 0 =None; 1 =Mild; 2 =More than mild
u. Amount of p	ortal, elifolite ilitialimiation. V-1volle, 1-1ville, 2-1viole than filling
15. Liver cell injury	V
	y 0=None → GOTO Item 15d; 1=Few; 2=Many
	oning present: 0=No; 1=Yes
	loon cells present: 0=No; 1=Yes
	odies: 0=Rare/absent; 1=Many
	nacrophages (Kupffer cells): 0=Rare/absent; 1=Many
	ondria: 0 =Rare/absent; 1 =Many
1. 1/1084111110011	ondria. V Taile deserti, I triany
16. Mallory-Denk l	bodies: 0=Rare/absent; 1=Many
_ 10/1/10/10/19 20/11/10	2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
17. Glycogen nucle	ei: 0 =Rare/absent; 1 =Present in patches
18. Glycogenosis o	of hepatocytes: 0 =Not present; 1 =Focal, involving less than 50% of the hepatocytes; 2 =Diffuse,
	ter than or equal to 50% of the hepatocytes
	1
19. Masson's trich	nrome stain
a. Fibrosis stag	e: 0=None → GOTO Item 20; 1a=Mild, zone 3 perisinusoidal (requires trichrome);
	ate, zone 3, perisinusoidal (does not require trichrome); 1c =Portal/periportal only;
	and periportal, any combination; 3=Bridging; 4=Cirrhosis
	lal fibrosis grade: 0=No perisinusoidal fibrosis present; 1=Perisinusoidal fibrosis present that
requires a l	Masson stain to identify; 2=Perisinusoidal fibrosis present that is visible on the H&E stain
	location of fibrosis: 0=More predominance around or between portal areas; 1=No portal or
	dominance; 2=More predominance around/between central veins
20. Iron stain	
a. Hepatocellul	ar iron grade: 0 =Absent or barely discernible, 40x → GOTO item 20c ;
1=Barely d	liscernable granules, 20x; 2 =Discrete granules resolved, 10x; 3 =Discrete granules resolved, 4x;
4=Masses	visible by naked eye
b. Hepatocellul	lar iron distribution: 0 =Periportal; 1 =Periportal and midzonal; 2 =Panacinar; 3 =Zone 3 or azonal
	ellular iron grade: 0 =None → GOTO item 21 ; 1 =Mild; 2 =More than mild
	ellular iron distribution: 0 =Large vessel endothelium only; 1 =Portal/fibrosis bands only, but
more than j	just in large vessel endothelium; 2 =Intraparenchymal only; 3 =Both portal and intraparenchymal
	patitis? 99=Not NAFLD; 0=NAFLD, not NASH; 1a=Suspicious/borderline/indeterminate: Zone
3 pattern; 1b =S	Suspicious/borderline/indeterminate: Zone 1, periportal pattern; 2 =Yes, definite
_ 22. Is cirrhosis pres	sent? $0=N_0 \rightarrow GOTO$ item 25; $1=Yes$
_ 23. Is this cryptoge	enic cirrhosis: 0=No → GOTO item 25; 1=Yes
	stive of steatohepatitis etiology for cryptogenic cirrhosis:
	nk bodies (rule out cholate stasis): 0=Absent; 1=Present
	al fibrosis away from septa: 0=Absent; 1=Present
	pallooning: 0=Absent; 1=Present
	ondria: 0=Absent; 1=Present
e. Other notabl	e findings: 0=Absent; 1=Present; Specify:
25 Other comment	
/3 Lither comment	

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 identification1. Center ID
	2. Patient ID
	3. Patient code
///	4. Date of central reading
	5. Visit code
<u>c r 3</u>	6. Form and revision
	7. Study: 6 =Database 2; 9 =STOP-NAFLD
///	8. Date of biopsy
	B. Slide sequence number9. 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):

 1 unem 1D
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
 d. Microvesicular sicatosis, contiguous patenes. V Mosent, T Tresent
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
 7.
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
involving greater than or equal to 30% of the nepatobytes
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 (<i>does not require trichrome</i>); 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, $40x \rightarrow GOTO$ item $20c$;
1 =Barely discernable granules, 20x; 2 =Discrete granules resolved, 10x; 3 =Discrete granules resolved, 4x;
4=Masses visible by naked eye
 b. Hepatocellular iron distribution: 0 =Periportal; 1 =Periportal and midzonal; 2 =Panacinar; 3 =Zone 3 or azonal
 c. Nonhepatocellular iron grade: 0=None → GOTO item 21; 1=Mild; 2=More than mild
 d. Nonhepatocellular iron distribution: 0 =Large vessel endothelium only; 1 =Portal/fibrosis bands only, but
more than just in large vessel endothelium; 2=Intraparenchymal only; 3=Both portal and intraparenchymal
21. Is this steatohepatitis? 99 =Not NAFLD; 0 =NAFLD, not NASH; 1a =Suspicious/borderline/indeterminate: Zone
 3 pattern; 1b =Suspicious/borderline/indeterminate: Zone 1, periportal pattern; 2 =Yes, definite
5 pattern, 10-suspicious/voruernne/indeterninate. Zone 1, periportal pattern, 2-1 es, 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 identification1. Center ID
	2. Patient ID
	3. Patient code
//	4. Date of central reading
	5. Visit code
<u>c</u> <u>r</u> <u>4</u>	6. Form and revision
_	7. Study: 10 =VEDS; 11 =Database 3
//	8. Date of biopsy
	B. Slide sequence number9. Sequence number for a. H & E stained slide
	b. Masson's trichrome stained slide
<u>—</u> .—	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 ()	ID
Patient	"

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 (<i>does not require trichrome</i>); 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
central predominance, 2–wore predominance around/between central venis
18. Iron stain
a. Hepatocellular iron grade: 0=Absent or barely discernible, 40x → GOTO item 20c;
1=Barely discernable granules, 20x; 2=Discrete granules resolved, 10x; 3=Discrete granules resolved, 4x;
4=Masses visible by naked eye
b. Hepatocellular iron distribution: 0=Periportal; 1=Periportal and midzonal; 2=Panacinar; 3=Zone 3 or azonal
c. Nonhepatocellular iron grade: 0=None → GOTO item 21; 1=Mild; 2=More than mild d. Nonhepatocellular iron distribution: 0=Large vessel endothelium only; 1=Portal/fibrosis bands only, but
more than just in large vessel endothelium; 2 =Intraparenchymal only; 3 =Both portal and intraparenchymal
19. Is this steatohepatitis? 99 =Not NAFLD; 0 =NAFLD, not NASH; 1a =Suspicious/borderline/indeterminate: Zone
3 pattern; 1b =Suspicious/borderline/indeterminate: Zone 1, periportal pattern; 2 =Yes, definite
20. Features of regression: 0 =No; 1 =Yes
21. Other comments:

HI - Follow-up Medical History

Purpose: To record follow-up medical history information about the patient. **When**: Visits t048, t096, t144, t192, t240, t288, t336, t384, t432, and t480. **Administered by**: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.

Instructions: Collect information by interview and chart review.

A. Center, visit, and patient identification

- **2.** Patient ID: ____ ___ ____
- **3.** Patient code: ____ ___
- **4.** Visit date (date this form is initiated):

_		_
day	mon	year

- **5.** Visit code: __t__ ___ ___
- **6.** Form & revision: <u>h i 1</u>
- 7. Study: NAFLD Database 2 6

B. Interval identification

8. Date of last Follow-up Medical History form (if this is visit t048 then date of t0):

day	mon	year

9. Visit code of last Follow-up Medical History form *(if this is visit t048 then t0):*

C. NAFLD evaluation

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

$$\binom{\text{Yes}}{*}$$
 $\binom{\text{No}}{2}$

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

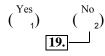
11. Has the participant had an upper abdominal imaging study since the last visit:

$$\binom{\text{Yes}}{*}$$
 $\binom{\text{No}}{2}$

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

D. Alcohol consumption (AUDIT-C) since the last visit

12. Is the patient age 12 or older:



13. Since the last visit, how often have you had a drink containing alcohol:

Never	()
	16.
Monthly or less	(1)
Two to four times a month	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
Two to three times a week	$\begin{pmatrix} & & \\ & & \end{pmatrix}$
Four or more times a week	(4)

14. Since the last visit, how many drinks containing alcohol have you had on a typical day when you are drinking:

15. Since the last visit, how often have you had six or more drinks on one occasion:

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

E. Tobacco cigarette smoking			r. Hepatic encephalopathy:	(1)
16. Since the last visit, have you smoked tobacco cigarettes regularly ("No" means smoked less than 1 day per week on average):		s. Portal hypertension:	(1)	
			t. Hepatorenal syndrome:	(1)
		No	u. Hepatopulmonary syndrome:	(1)
$\begin{pmatrix} \text{Yes} \\ \begin{pmatrix} 1 \end{pmatrix} \end{pmatrix}$	(2)	v. Short bowel syndrome:	(1)
19.	· 	J	w. Hemophilia (bleeding disorder):	(1)
17. On average, how many days per week have you smoked cigarettes:			x. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus:	(1)
	# d	lays	y. Endocrine disease	,	
18. On the days that you smoked, about			(hormonal abnormality):	(1)
how many cigarettes did you smoke per day:			z. Hepatocellular carcinoma:	(1)
per day.			aa. Other malignancy (cancer):	(1)
# cigarettes	nor d	lov.	ab. Peripheral neuropathy:	(1)
-	per u	iay	ac. Seizure disorder or epilepsy:	(1)
F. Medical history			ad. Drug allergies:	(1)
19. Since the last visit, has the patient been		ae. Hypothyroidism:	(1)	
diagnosed with or treated for any of the following (check all that apply; source of information can be interview and/or chart review)			af. Hypertension:	(1)
			ag. Cerebrovascular disease:	(1)
a. Diabetes type 1:	(1)	ah. Dysbetalipoproteinemia:	(1)
b. Diabetes type 2:	(1)	ai. Hyperlipidemia (high cholesterol, high triglycerides):	(1)
c. Gestational diabetes	(`	aj. Pancreatitis:	(1)
(diabetes of pregnancy):	(1)	ak. Cholelithiasis:	(1)
d. Hepatitis B:	(1)	al. Coronary artery disease:	(1)
e. Hepatitis C:	(1)	am. Elevated uric acid such as gout:	(1)
f. Autoimmune hepatitis:	(1)	an. Kidney disease:	(1)
g. Autoimmune cholestatic liver disorder (PBC or PSC):	(1)	ao. Polycystic ovary syndrome:	(1)
h. Wilson's disease:	(1)	ap. Sleep apnea (not breathing during	,	
i. Alpha-1-antitrypsin (A1AT) deficiency:	(1)	sleep):	(1)
j. Iron overload:	(1)	aq. Dermatologic disorders:	(1)
k. Drug induced liver disease:	(1)	ar. Myopathy:	(1)
l. Gilbert's syndrome:	(1)	as. Myositis:	(1)
m. Esophageal or gastric varices on	`	12	at. Major depression:	(1)
endoscopy:	(1)	au. Schizophrenia:		1)
n. Bleeding from varices:	(1)	av. Bipolar disorder:	(1)
o. Other gastrointestinal bleeding:	(1)	aw. Obsessive compulsive disorder:	(1)
p. Ascites:	(1)	ax. Severe anxiety or personality disorder:	(1)
q. Edema:	(1)	ay. None of the above:	(1)

20.	Since the last visit, has the patient had surgery for any of the following (check all that apply)		
	a. Stapling or banding of the stomach:	(1)
	b. Jejunoileal (or other intestinal) bypass:	(1)
	c. Biliopancreatic diversion:	(1)
	d. Other GI or bariatric surgery (specify):	(1)
	e. None:	(1)
21.	Since the last visit, has the patient received an organ, limb, or bone marrow		

transplant:

No

22. Since the last visit, has the patient received total parenteral nutrition (TPN):

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



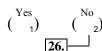
24. Since the last visit, has the patient been hospitalized:



If Yes, specify reason:

specify reason

25. Since the last visit, has the patient had any serious health problem not already reported:



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)

	Vac	ν.	lo
	Yes (1)	(2)
	2	7.	J
a. Acarbose (Precose):		(1)
b. Acetohexamide (Dymelor):		(1)
c. Chlorpropamide (Diabinese):		(1)
d. Glimepiride (Amaryl):		(1)
e. Glipizide (Glucotrol, Glucatro	ol XL):	(1)
f. Glyburide (Micronase, DiaBe Glynase):	ta,	((ر
g. Insulin:		(1)
h. Metformin (Glucophage, GluXR):	cophage	(1)
i. Miglitol (Glycet):		(1)
j. Nateglinide (Starlix):		(1)
k. Pioglitazone (Actos):		(1)
l. Repaglinide (Prandin):		(1)
m. Rosiglitazone (Avandia):		(1)
n. Tolazamide (Tolinase):		(1)
o. Tolbutamide (Orinase):		(1)
p. Other, (specify):		(1)

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

Y	'es	N	lo
(1)	(2

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

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	29.

- a. Atorvastatin (Lipitor): (1)
 b. Colestipol hydrochloride (Colestid): (1)
 c. Clofibrate (Abitrate, Atromid-S, Claripex Novofibrate): (1)
- Claripex, Novofibrate): (1) **d.** Gemfibrozil (Gen-Fibro, Lopid): (1)
- e. Fenofibrate (Tricor):
- **f.** Fluvastatin sodium (Lescol):
- g. Lovastatin (Mevacor):
- h. Nicotinic acid (Niaspan): (1)
- i. Pravastatin sodium (Pravachol): $\binom{1}{1}$ j. Rosuvastatin (Crestor): $\binom{1}{1}$
- **k.** Simvastatin (Zocor): (1) **l.** Other, (*specify*): (1)
- **29.** Since the last visit, has the patient taken any antiobesity medications:

Y	es	N	lo
(1)	(2)

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

Yes	No	
$\begin{pmatrix} & & 1 \end{pmatrix}$	(;	2)

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

	(1)	(2)
		3	2.	
mioderana (Decerona):			(`

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

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*)

$\binom{\text{Yes}}{1}$	$\binom{No}{2}$
	33.

- **a.** Oral contraceptives: (
- **b.** Raloxifene (Evista):
- c. Tamoxifen (Nolvadex):
- **d.** Other, (specify):

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

	Yes	N	0 \
	(1)	_ (2)
	3	34.	
a. MultiVitamin:		(1)
b. Vitamin B (any type):		(1)
c. Vitamin C:		(1)
d. Vitamin D:		(1)
e. Vitamin E:		(1)
f. Alpha-lipoic acid:		(1)
g. Alpha-tocopherol:		(1)
h. Beta-carotene:		(1)
i. Betaine (Cystadane):		(1)
j. Calcium (any form):		(1)
k. Carnitine (any form):		(1)
l. Choline + methionine + beta			
adenosine + pyridoxine (Ep	ocler):	(1)
m. Cod liver oil:		(1)
n. Coenzyme Q:		(1)
o. Echinacea:		(1)
p. Fish oil (any form):		(1)
q. Flax seed oil:		(1)
r. Garlic:		(1)
s. Ginkgo biloba:		(1)
t. Glucosamine (any form):		(1)
u. Lecithin:		(1)
v. Milk thistle:		(1)
w. N-acetyl-cysteine:		(1)
x. S-adenylmethionine (SAM-	-e):	(1)
y. Saw palmetto:		(1)
z. Selenium:		(1)
aa. St. John's Wort:		(1)
ab. Taurine:		(1)
ac. Zinc picolinate:		(1)
ad Other (specify):		(.)

year

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

(IJ yes, cneck all that apply)		
$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$	(N	No 2)
35.]—	_ ا
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)

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

o. Other, (specify):



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	(,

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:	
•	Diady	1 II y Si Ciuii	oigilatare.	

day

41.	Date form reviewed:	

mon

IE - Interim Event Report

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

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

Administered by: Study Physician and Clinical Coordinator.

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

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

A. Center, patient, and visit identification	10. Gender:		
1. Center ID:	Male	(1)
	Female	(2)
2. Patient ID:	11. Age at time of event:		
	C	years	
3. Patient code:	D. Event description		
4. Date of report:	12. Date event started:		
day mon year	day mon	year	
5. Visit code:	13. Nature of event (check all that apply)		
<u>n</u>	a. General anesthesia	(1)
6. Form & revision:ie1_	b. Study procedure related event:	(1)
NAELD Database 2 6	c. Drug interactions:	(1)
7. Study: NAFLD Database 2 <u>6</u>	d. Worsening of a co-morbid illness:	(1)
B. Visit interval identification	e. Hypoglycemia:	(1)
	f. New-onset diabetes:	(1)
8. Most recently completed visit (screening or follow-up)	g. Pregnancy (patient):	(1)
a. Date:	h. Other (specify):	(1)
day mon year			
b. Visit code:			
	14. Did the event lead to (check all that ap	ply)	
C. Patient information	a. Emergency room visit:	(1)
9. Date enrolled in NAFLD Database 2	b. Hospitalization:	(1)
Study (enter n if patient is not yet enrolled):	c. Infectious episode:	(1)
day mon year	d. Surgical intervention:	(1)

			Patient ID:
15. Describe event:			20. Other comments on event:
16. Short name for event if applicable (short for AEs are listed in the CTCAE v3.0 d available at www.nashcrn.com; click o ments and then click on General Docume	locun n De	nent ocu-	F. Administrative information 21. Clinical Coordinator PIN:
Not applicable	((0	22. Clinical Coordinator signature:
17. Severity grade (severity grades are liste CTCAE v3.0 document availa www.nashcrn.com; click on Documents click on General Documents):	ıble	a t	23. Study Physician PIN:
Not applicable	((0	
Grade 1 - Mild	(1)	
Grade 2 - Moderate	(2)	25. Date form reviewed:
Grade 3 - Severe	(3)	
Grade 4 - Life threatening or disabling	(4)	day mon year
Grade 5 - Death	(*5)	Key this form and fax the DCC (Attention: Pat
*Complete and key Death Report (DR) fo	orm.		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
18. Date event resolved (enter n if event is resolved):	not	yet	and timely study wide review. The received re- ports will be reviewed by Jeanne Clark, the Safety Officer, for appropriate further review by the Steering Committee and Data and Safety Monitor-
day mon	year		ing Board.
19. What action was taken:			

IE - Interim Event Report

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

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

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at https://jhuccs1.us/nash/default.asp. Click on Documents and then click on General Documents. Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).

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

A. Center, patient, and visi	t identification	C. Patient information		
1. Center ID:		9. Date enrolled in NAFLD Database 2 Study (enter n if patient is not yet enrol	led):	
2. Patient ID:			year	
3. Patient code:		10. Gender:	year	
4. Date of report:		Male Female	(1) 2)
	mon year	11. Age at time of event:	years	
5. Visit code:	_n	D. Event description	,	
6. Form & revision:	_ie2_	12. Date event started:		
7. Study: NA	FLD Database 2 <u>6</u>	day mon	year	
B. Visit interval identificat	ion	13. Nature of event (check all that apply)		
8. Most recently complete or follow-up)	ed visit (screening	a. General anesthesiab. Study-related procedure:	(1) 1)
a. Date:		c. Drug interactions:	(1)
	mon year	d. Worsening of a co-morbid illness:e. Hypoglycemia:	(1) 1)
b. Visit code:		f. New-onset diabetes:	(1)
		g. Pregnancy (patient):	(1)
		h. Cirrhosis:	(1)
		i. Hepatocellular carcinoma (HCC):* Complete and key the HC form.	(*	[*] ₁)
		j. Other (specify):	(1)

14. Did the event lead to (check all that ap	oply)	18. Date event resolved		
a. Emergency room visit:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	(enter n if event is not yet resolved):		
b. Hospitalization:	(1)	day mon year		
c. Infectious episode:	(1)	ddy mon yeu		
d. Surgical intervention:	(1)	19. What action was taken:		
15. Describe event:				
		20. Other comments on event:		
16. Indicate the name for the event obtainfrom the NCI's Common Terminology Criteria for Adverse Events (CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp Documents and then click on Gen	y o; click on			
ments):				
a. Not in CTCAE (e.g. malignancy, d.	ata	F. Administrative information		
breach) (specify):	(1)	21. Clinical Coordinator PIN:		
		22. Clinical Coordinator signature:		
17. Indicate the severity code using the CTCAE grading scale for the AE specified (severity grades are listed in	the	23. Study Physician PIN:		
CTCAE v3.0 document ava https://jhuccs1.us/nash/default.asp Documents and then click on Gen ments):	o; click on	24. Study Physician signature:		
Grade 1 - Mild	(1)			
Grade 2 - Moderate	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	25. Date form reviewed:		
Grade 3 - Severe†	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	_		
Grade 4 - Life threatening or disabling	g† (₄)	day mon year		
Grade 5 - Death†	(* 5)	Key this form and far the DCC (Attention: Po		

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.

†Fax the DCC (Attention Pat Belt) a copy

*Complete and key Death Report (DR) form.

of this form if severity grade is 3 or higher (Fax 410-955-0932).

IE - Interim Event Report

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

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

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 16) and the severity code (item 17) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at https://jhuccs1.us/nash/default.asp. Click on Documents and then click on General Documents. Fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher (Fax 410-955- 0932).

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

A. Center, patient, and visi	t identification	C. Patient information		
1. Center ID:		9. Date enrolled in NAFLD Database 2 Study (enter n if patient is not yet enrolled)	lled):	
2. Patient ID:			year	
3. Patient code:		10. Cardan	,	
		10. Gender:	,	
4. Date of report:		Male	(1/
=	=	Female	(2
day	mon year	11. Age at time of event:		
5. Visit code:		-	years	
3. Visit code:	<u>n</u>	D. Event description		
		D. Event description		
6. Form & revision:	<u>i e 3</u>	12. Date event started:		
7. Study: NA	FLD Database 2 <u>6</u>	day mon	year	
B. Visit interval identificat	ion	13. Nature of event (check all that apply)		
		a. General anesthesia	(1/
8. Most recently complete or follow-up)	d visit (screening	b. Study-related procedure:	(1/
a. Date:		c. Drug interactions:	(1/
a. Date	_	d. Worsening of a co-morbid illness:	(1/
day	mon year	e. Hypoglycemia:	(1/
b. Visit code:		f. New-onset diabetes:	(1/
		g. Pregnancy (patient):	(1/
		h. Cirrhosis:	(1/
			()	1/ k \ 1/
		i. Hepatocellular carcinoma (HCC):* Complete and key the HC form.	('	1,

14. Did the event lead to (check all that apply)		18. Date event resolved			
	a. Emergency room visit:	(1.)	(enter n if event is not yet resolved):
	b. Hospitalization:	(1.)	day mon year
	c. Infectious episode:	(1.)	uay mon year
	d. Surgical intervention:	(1)	19. What action was taken:
15.	Describe event:				
				_	
				_	
				-	
				_	
				_	20. Other comments on event:
16.	Is the event listed in the NCIs Common				
	Terminology Criteria for Adverse Events (CTCAE v3.0 document available at https://jhuccs1.us/nash/default.asp; click on Documents and then click on General				
	Documents): Yes (1)		No ,)	
	· ·	(2	,	
	a. Indicate the name of the event (if in the CTCAE, specify name exactly from document; if not in CTCAE specify name):				F. Administrative information
	specify name).				21. Clinical Coordinator PIN:
				_	22. Clinical Coordinator signature:
17.	Indicate the severity code using the CTCAE grading scale for the AE				
	specified (severity grades are listed in the CTCAE v3.0 document availa https://jhuccs1.us/nash/default.asp; c	ble click	01	n	23. Study Physician PIN:
	Documents and then click on Genera ments):	I Do	си	!-	24. Study Physician signature:
	Grade 1 - Mild	(14)	
	Grade 2 - Moderate	(2		
	Grade 3 - Severe†	(3,		25. Date form reviewed:
	Grade 4 - Life threatening or disabling†	(4		20. Sate form fortered.
	Grade 5 - Death†	(;			day mon year
	† Fax the DCC (Attention Pat Belt) a copy of this form if severity grade is 3 or hig		Fa	X	Key this form and fax the DCC (Attention: P Belt) a copy of this form if severity grade is 3

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.

410-955-0932).

*Complete and key Death Report (DR) form.

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:	10. Findings suggestive of NAFLD, NASH-related cirrhosis, or others of significance (check all that apply)			
	a. Fatty infiltration:	(12	
2. Patient ID:	b. Cirrhosis:	(12	
3. Patient code:	c. Hepatomegaly:	(12	
	d. Hepatic mass:	(12	
4. Date of visit:	e. Intrahepatic biliary dilatation:	(12	
	f. Extrahepatic biliary dilatation:	(12	
day mon year	g. Gallstones/cholelithiasis:	(12	
5. Visit code:	h. Gall bladder polyps:	(12	
	i. Cholecystectomy:	(12	
6. Form & revision:ir1	j. Splenomegaly:	(12	
7. Study: NAFLD Database 2 6	k. Ascites:	(12	
B. Upper abdominal ultrasound	l. Other features of portal hypertension (specify):	(1/	
8. Did the patient have an upper abdominal ultrasound in the past 6 months (screening)/since the last visit (follow-up): Yes No 2	m. Other abnormality (specify):	(1)	
9. Date of most recent upper abdominal ultrasound:	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	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2
	14.

1)

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)*

d. Hepatic mass:

a. Fatty infiltration:	
b. Cirrhosis:	
c. Hepatomegaly:	

- e. Hepatic hemangioma: (1)

 f. Hepatic cyst: (1)
- **g.** Intrahepatic biliary dilatation:
- h. Extrahepatic biliary dilatation: (1)
 i. Gallstones/cholelithiasis: (1)
- j. Gall bladder polyps:
- **k.** Cholecystectomy: (1) **l.** Splenomegaly: (1)
- m. Ascites:

 ()

 Other features of portal

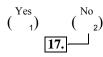
hypertension (specify):

o. Other abnormal	ity (specify):	(1/

p. None of the above:

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*):



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)
	C' 1 '	1	`

D. CHIHOSIS.	(1)
c. Hepatomegaly:	(1)

d. Hepatic mass:	(1)

e. Hepatic hemangioma:	(1)
f. Henatic cyst:	(

	(17
g. Intrahepatic biliary dilatation:	(1)

l.	Other abnormality (specify):	(1)

m. None of the above:	((ر

Patient ID:	 	

E. Administrative information

day

17.	Study Physician PIN:
18.	Study Physician signature:
19.	Clinical Coordinator PIN:
20.	Clinical Coordinator signature:
21.	Date form reviewed:

mon

year

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 to. 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.

٨	Contar	patient.	and	wieit	idon	tifico	tion
Α.	Center.	patient.	ana	VISIT	ıaen	unca	uon

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):



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."

How old were you when you began regular drinking:

a. Years:

b. Months:

How old were you at the end of first stage:

Years:

yrs

yrs

b. Months:

mos

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

drinks

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

days

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

%

How would you rate your usual style of drinking during an average month (check the appropriate category);

Abstinent Occasional (less than 15 days) Weekend mainly Binge (at least 3 days heavy drinking)

Frequent (15 days or more per month)

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



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

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

Patient ID:		

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	 0/	

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":



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:

	ora were you at the one or this	p11450.
a.	Years:	
h	Months:	yrs
D.	Wolfins.	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:



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):

cjjec						_
	Pos	sitive	Neg	gative	Ne	utral
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 (,)	Ì	2)	(₂)

Patient ID:		

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 No

81. 4

33. How old were you at the beginning of the phase:

a. Years: ________ **b**. Months: _______

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"):

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)

Patient ID:		

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

Y	es	N	Ю
(1)	(2)
	42]4	

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):

		Posit	ive	Neg	ative	Ne	utral
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"):

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":



45. How old were you at the beginning of the phase:

a. Years: _____yrs

b. Months:

46. How old were you at the end of this phase:

a. Years: _____yrs

b. Months:

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.)

Patient ID:		

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:



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):

		Posit	ive	Neg	ative	Ne	utral
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)
\mathbf{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":



57. How old were you at the beginning of the phase:

a.	Years:	
		yrs
b.	Months:	
		moe

58. How old were you at the end of this phase:

a.	Years:	
		yrs
b.	Months:	<u></u>
		mos

Patient ID:		

59.	During this phase, how many drinks would you have on average per occasion (drinking day):
60.	# drinks How many days per month would you generally drink at this level (write "m" if not drinking):
61.	# days 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

Beer		should be "000").
	%	Alone
Liquor	<u></u>	
	70	With others
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:



55. 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):

		Posit	ive	Neg	ative	Ne	utral
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	 <u>%</u>	

Patient ID:		

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		N	lо
(1)	(2)
	81]	

69. How old were you at the beginning of the phase:

a.	Years:	
		yrs

- **b**. Months:
- **70.** How old were you at the end of this phase:

a.	rears:	
		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*):



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



(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:



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):

		Posit	ive	Neg	gative	Ne	utral
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	. (,)	(<u>_</u>)	(2)

78.	What percentage of time and what percentage of to other person (record the "Alone" and "With othe add up to 100%; if not dishould all be "000"):	he time with at least one relative percentages of rs"; this section should
	Alone	<u> </u>
	With others	
79.	During what time of the of your drinking? Could percentage of time during and morning (record the morning, afternoon and should add up to 100%; percentages should all be	you give me the g the evening, afternoon relative percentages of evening; this section if not drinking,
	Morning	
	Afternoon	
	Evening	
I. Nu	mber of phases	
80.	Are there any additional	subsequent phases: Yes No (* 1) (2)
	* If yes, complete a secon Skip sections B and C on	

J. Administrative information

83. Date form reviewed:

Clinical Coordinator PIN:

Clinical Coordinator signature:

mon

81.

82.

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 <u>required</u> 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	12. White blood cell cou	int (WBC):	
1. Center ID:		10^{3} cells/ μ L or 10^{9} cells/L	
2. Patient ID:	13. Platelet count:		
3. Patient code:		•	
3. I attent code		τοπο, μ.Ε.	
4. Date of visit (date form was initiated):	C. Chemistries and HbA	.1c	
	14. Date of blood draw f	for chemistries:	
day mon year			
5. Visit code:t	day Date must be withir	mon year n the required time window;	
6. Form & revision:	within 3 months of screening or in the time windo for the follow-up visit (check the patient's Data base 2 visit time window guide).		
7. Study: NAFLD Database 2 6	15. Blood urea nitrogen	(BUN):mg/dL	
B. Hematology	16. Creatinine:	•	
8. Date of blood draw for complete blood		mg/dL	
count:	17. Uric acid:	<u> </u>	
day mon year		mg/uL	
Date must be within the required time window; within 3 months of screening or in the time window	18. Date of blood draw f	or HbA1c:	
for the follow-up visit (check the patient's Database 2 visit time window guide).	day	mon year	
	Date must be within within 3 months of sc	n the required time window; reening or in the time window	
9. Hemoglobin:	for the follow-up vis base 2 visit time win	sit (check the patient's Data- dow guide)	
_	ouse 2 visit time with	uon guiuc).	
10. Hematocrit:	19. HbA1c:		
		%	
11. Mean corpuscular volume (MCV):			

D. Liver panel

20. Date of blood draw for liver panel:

		<u></u>
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):
- 22. Bilirubin (direct):
- 23. Aspartate aminotransferase (AST)

a. Upper limit of normal:	

24. Alanine aminotransferase (ALT)

a. Upper limit of normal:	U/L

25. Alkaline phosphatase

28. Albumin:

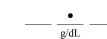
	O/L
a. Upper limit of normal:	
11	T T/T

26. Gamma glutamyl transferase (GGT):

	U/L	
	•	

T I/I

27. Total protein: g/dL



- **29.** Prothrombin time (PT):
- **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:

$$\binom{\text{Yes}}{1}$$
 $\binom{N_0}{*}$

*12 hour fasting is preferred, but will accept nonfasting lipid values.

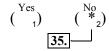
32. Date of blood draw for lipid profile:

	day	mon	year
within 3 m for the for	t be within the conths of screen llow-up visit (c it time window	iing or in th check the p	e time window
a. Triglyc	erides:		mg/dL
b. Total c	holesterol:		mg/dL
c. HDL cl	nolesterol:		mg/dL
d. LDL cl	nolesterol:		

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:



mg/dL

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

mon

year

37. Clinical Coordinator PIN:

39. Date form reviewed:

38. Clinical Coordinator signature:

LR - Laboratory Results - Tests Done During NAFLD Database 2 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 <u>required</u> 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	12. White blood cell count (WBC):
1. Center ID:	$\frac{\bullet}{10^3 \text{ cells/}\mu\text{L or } 10^9 \text{ cells/L}}$
2. Patient ID:	13. Platelet count:
3. Patient code:	
4. Date of visit (date form was initiated):	C. Chemistries and HbA1c
day mon year	14. Date of blood draw for chemistries:
5. Visit code:	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 Data- base 2 visit time window guide).
7. Study: NAFLD Database 2 6	15. Blood urea nitrogen (BUN):mg/dL
B. Hematology	16. Creatinine: • mg/dL
8. Date of blood draw for complete blood count:	17. Uric acid:
day mon year Date must be within the required time window; within 90 days of screening or in the time window	18. Date of blood draw for HbA1c:
for the follow-up visit (check the patient's Database 2 visit time window guide).	day mon year Date must be within the required time window;
9. Hemoglobin:	within 90 days of screening or in the time window for the follow-up visit (check the patient's Data- base 2 visit time window guide).
10. Hematocrit:	19. HbA1c:
11. Mean corpuscular volume (MCV):	

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).

- 23. Aspartate aminotransferase (AST)

a. Upper limit of normal:	

24. Alanine aminotransferase (ALT)

a. Upper limit of normal:	U/L

- **26.** Gamma glutamyl transferase (GGT):

U/L	

- **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:

$$\binom{\text{Yes}}{1}$$
 $\binom{N_0}{*}$

*12 hour fasting is preferred, but will accept nonfasting lipid values.

32. Date of blood draw for lipid profile:

day	mon	year
Date must be within the within 90 days of screen for the follow-up visit base 2 visit time window	ning or in the check the p	e time window
a. Triglycerides:		mg/dL
b. Total cholesterol:		

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:



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

		day	mon		year
	within 9 for the f base 2 v cose and	ust be within days of scroollow-up visisit time wire insulin valu	reening or sit (check t adow guide	in the t the pat e). The	ime window ient's Data serum glu
	a. Serun	n glucose:			mg/dL
	h Serun	n insulin:			mg/uL ●
	b. Scrun	i ilisailii.		μU/mI	<u> </u>
G. A	dministi	ative infori	nation		
35.	Study Ph	ysician PIN	:		
36.	Study Pł	ıysician sign	ature:		
37.	Clinical	Coordinator	PIN:		
38.	Clinical	Coordinator	signature:		
39.	Date for	n reviewed:			
			mon		year

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	12. Blood cell count	
1. Center ID:	a. White blood cell count (WBC):	
2. Patient ID:	10 ³ cells/μL or 10 ⁹ cells/L b. Red blood cell count (RBC):	
3. Patient code:	<u> </u>	
4. Date of visit (date form was initiated):	mill cells/μL 13. Platelet count:	
day mon year	,,	
5. Visit code:t	C. Chemistries and HbA1c	
6. Form & revision:	14. Date of blood draw for chemistries:	
7. Study: NAFLD Database 2 <u>6</u>	day mon year	
B. Hematology8. Date of blood draw for complete blood count:	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).	
day mon year	15. Blood urea nitrogen (BUN):mg/dL	
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).	16. Creatinine:	
9. Hemoglobin:	17. Uric acid:	
10. Hematocrit:	18. Date of blood draw for HbA1c:	
11. Mean corpuscular volume (MCV): fL	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 Data- base 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

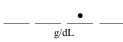
a. Upper limit of normal:

U/L	

26. Gamma glutamyl transferase (GGT):

U/L	

27. Total protein:



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:

$$\binom{\text{Yes}}{1}$$
 $\binom{N_0}{*}$

*12 hour fasting is preferred, but will accept nonfasting lipid values.

32. Date of blood draw for lipid profile:

	_		_		
day		mon		vear	

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).

b. Total cholesterol:	
	mg/dL

c. HDL cholesterol: _____ mg/dL ____

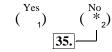
d. LDL cholesterol*:	
	mg/dL

*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:



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

34.	Date of bloo and insulin l	d draw for f evels:	fasting gluco	se
	within 90 da	iys of screen	iing ôr in the	 year time window; time window
	base 2 visit	time windo ulin value sl	w guide). ÎT	ntient's Data- he serum glu- uined from the

a. Serum glucose:	
· ·	mg/dL
b. Serum insulin:	•
	μU/mL

G. Administrative information

39.

35.	Study Physician PIN:
36.	Study Physician signature:
37.	Clinical Coordinator PIN:
38.	Clinical Coordinator signature:

Date form reviewed:		
	mon —	

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	B. Screening etiologic tests		
1. Center ID:	10. Date of blood draw for serological assays to exclude viral causes of chronic liver		
2. Patient ID:	disease:		
3. Patient code:	day mon year Repeat if date is greater than 5 years prior to screening.		
4. Date of visit:	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.		
day mon year 5. Visit code: <u>t 0</u>	a. Hepatitis B surface antigen (HBsAg): Positive		
6. Form & revision:	Negative (2)		
7. Study: NAFLD Database 2 6	b. Hepatitis B core total antibody (anti-HBc) (if total anti-HBc is not available, record results from IgG test):		
8. Is the patient a continuing participant from Database, PIVENS, or TONIC:	Positive (1) Negative (2)		
(Yes (No *2) 10. 10. 10. 10. 10. 10. 10. 10. 10. 10.	Not available (3) c. Hepatitis B surface antibody (anti-HBs): Positive (1) Negative (2)		
9. Are new laboratory results available for the continuing participant: (Yes (* 1) (No 2)	Negative Not available d. Hepatitis C antibody (anti-HCV) (indicate result as negative if EIA is positive but RIBA is negative or if RIBA is indeterminate but HCV RNA is negative): Positive		
*Record the date of blood draw as 'm'' if a test was not done.	Negative (2)		

e.	Hepatitis	C	virus	RNA

Positive



Negative Not available

 $\begin{pmatrix} & & & \\ & & & \\ & & & \end{pmatrix}$

f. Hepatitis A virus antibody (anti-HAV, total):

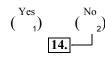
Positive	(1)
Negative	(2)
Not available	(3)

C. Iron

11. Date of blood draw for iron overload screening:

_		=
day	mon	year
Repeat if date is greater screening.	than	5 years prior to
a. Iron:		

- **b.** Total iron binding capacity: ____ μ_g/dL
- **12.** Is hepatic iron index available:

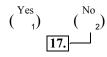


13. Hepatic iron index:



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+:



15. Date of blood draw for HFE gene analysis:

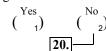
_		_
day	mon	year

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	(ر ا

E. Ceruloplasmin

17. Is patient 40 years old or younger:



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 ______ ___ ____
 - 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	vear

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

21. Alpha-1 antitrypsin (A1AT) _____ mg/dL ____

a. Upper limit of normal:	
	Č

- **b.** Lower limit of normal: _____ mg/dL ____
- **22.** A1AT phenotype:

Yes

a. Pi Z heterozygote:

No	(2)
Unknown	(3)
b. Pi ZZ homozygote:		
Yes	(1)

Yes	(1
No	(2)

- Unknown (3)
- 23. A1AT deficiency (physician judgment):



1)

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	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	26.

- *If positive ANA value, complete either a or b depending on laboratory results:
- **a.** Titer (record only the denominator):

1/	

b. Units:	<u> </u>

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/	 	
	•	

27. Antimitochondrial antibody (AMA):

b. Units:

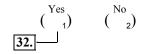
Positive	(*1)
Negative	(2)
Age < 18 and not done	28

*If positive AMA value, complete either a or b depending on laboratory results:

a. Titer (record only the plenominator):

b. Units:	•

28. Is patient 18 or older:



29. Lymphocytotoxic antibody (LCA):

Positive	$\begin{pmatrix} * \\ 1 \end{pmatrix}$
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 plenominator):

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

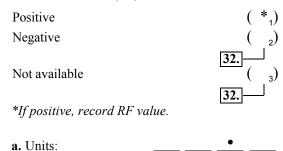


*If positive LKM1 value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/		

- **31.** Rheumatoid factor (RF):

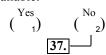


IU/mL.

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:



33. Date of blood draw for immunoglobulin levels:

=	-	=
day	mon	year

- **34.** IgA: _____ mg/dL
- **36.** IgM: ______ mg/dL _____

I. Other screening blood tests

37. Date of blood draw for thyroid stimulating hormone (TSH)*:

		_			_		
=	day		mon			year	
neat i	f date is	greater	than	5	vears	prior	te

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	B. Screening etiologic tests
1. Center ID:	10. Date of blood draw for serological assays to exclude viral causes of chronic liver
2. Patient ID:	disease:
3. Patient code:	day mon year Repeat if date is greater than 5 years prior to screening.
4. Date of visit:	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.
5. Visit code:t0	a. Hepatitis B surface antigen (HBsAg): Positive
6. Form & revision:	Negative (2)
 7. Study: NAFLD Database 2 6 8. Is the patient a continuing participant from Database, PIVENS, or TONIC: 	b. Hepatitis B core total antibody (anti-HBc) (if total anti-HBc is not available, record results from IgG test): Positive (1)
$\binom{\text{Yes}}{1}$ $\binom{N_0}{*}{2}$	Not available (3)
*All laboratory test results are required during	c. Hepatitis B surface antibody (anti-HBs):
screening.	Positive (1)
	Negative (₂)
9. Are new laboratory results available for the continuing participant:	Not available $\binom{3}{3}$
Yes (* ₁) (No ₂) 39.	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
*Record the date of blood draw as "m" if a test was not done.	is negative): Positive(

Negative

Positive



Not available	

Negative

f. Hepatitis A virus antibody (anti-HAV, total):

Positive Negative Not available

C	Iron	

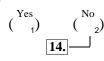
11. Date of blood draw for iron overload screening:

	day			mon			year	
Repeat if screening		is	greater	than	5	years	prior	te
a. Iron:						uջ		
						F-0		

b.	Total iron	binding	capacity:	 	
				μg/dL	

c. Ferritin:	
	ng/mL

12. Is hepatic iron index available:

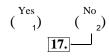


13. Hepatic iron index:



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+:



15. Date of blood draw for HFE gene analysis:

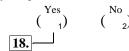
_	_	_
day	mon	year

16. Type of abnormality (WT = wild type; check only one):

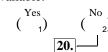
None	(0)
C282Y/H63D heterozygote mutation	(1)
C282Y/C282Y homozygote mutation	(2)
C282Y/WT heterozygote mutation	(3)
H63D/WT heterozygote mutation	(4)
H63D/H63D homozygote mutation	(5)

E. Ceruloplasmin

17. Is patient 40 years old or younger:



a. Is a ceruloplasmin value available:



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):

mon	year
ater than 10 y	ears prior to

- **19.** Ceruloplasmin mg/dL **a.** Upper limit of normal: __
 - **b.** Lower limit of normal: _

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 ____

 - **b.** Lower limit of normal: $\underline{\hspace{1cm}}_{mg/dL} \underline{\hspace{1cm}}_{mg/dL}$
- 22. A1AT phenotype:
 - **a.** Pi Z heterozygote: Yes

1 68	(1)
No	(2)
Unknown	(3)
b. Pi ZZ homozygote:		
Yes	(1)
No	(2)

23. A1AT deficiency (physician judgment):



3)

G. Autoantibody studies

Unknown

24. Date of blood draw for autoantibody tests:

	day	_=	mon		vear
a+	•	anaatan		5	una nuian t

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

25. Antinuclear antibody (ANA):

	J \ /	
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/	 	

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/	 	

27. Antimitochondrial antibody (AMA):

b. Units:

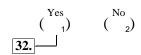
Positive	(*,
Negative	(2
Age < 18 and not done	28. (
	28.

*If positive AMA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/	 	

- 28. Is patient 18 or older:



29. Lymphocytotoxic antibody (LCA):

Positive	(* ₁)
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/		

30.	Antibod	to liver-kidney microsoma
	antigen (LKM1):

U ()	
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/		

31. Rheumatoid factor (RF):

b. Units:



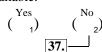
3.1

a. Units:	•
	IU/mL
If results are given as a	titer record as "n" and

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:



mg/dL

33. Date of blood draw for immunoglobulin levels:

	 mon	year
34. IgA:	_	mg/dL
35. IgG:		mg/dL

I. Other screening blood tests

37. Date of blood draw for thyroid stimulating hormone (TSH)*:

day		mon			year	
eat if date is	greater	than	5	vears	prior	te

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

36. IgM:

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	B. Screening etiologic tests
1. Center ID:	10. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:
2. Patient ID:	uiscase.
3. Patient code:	day mon year Repeat if date is greater than 5 years prior to screening.
4. Date of visit:	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.
5. Visit code:t0	a. Hepatitis B surface antigen (HBsAg): Positive
6. Form & revision:	Negative (2)
 7. Study: NAFLD Database 2 6 8. Is the patient a continuing participant from Database, PIVENS, or TONIC: 	b. Hepatitis B core total antibody (anti-HBc) (if total anti-HBc is not available, record results from IgG test): Positive (1) Negative (2)
10	Not available (3)
*All laboratory test results are required during screening.	c. Hepatitis B surface antibody (anti-HBs): Positive (,)
	Negative (2)
9. Are new laboratory results available for the continuing participant:	Not available (3)
*Record the date of blood draw as "m" if a test was not done.	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

Negative

e.	Hepatitis	C	virus	RNA
c.	riepanus	C	viius	INIA

Positive

Negative



Not avail	lat	ole	
Henatitic	Δ	virus	antibod

(anti-HAV, total):

Positive Negative

Not available

C. Iron

11. Date of blood draw for iron overload screening:

day	mon	year
at if date is grea	ter than 5 v	ears prior t

Repea screening.

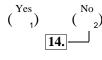
a. Iron:	
	$\mu g/dL$

b. Total iron binding capacity:
$$\underline{\qquad}_{\mu g/dL}$$

	E '	
c.	Ferritin	:

 ng/mL	

12. Is hepatic iron index available:

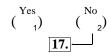


13. Hepatic iron index:

•	
μMo1/g/year	

D. HFE gene analysis

14. Does the patient have an abnormality in an iron overload screening test, a family history of iron overload or hemochromatosis, or histological iron of greater than 3+:



15. Date of blood draw for HFE gene analysis:

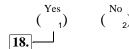
_		_
day	mon	year

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:



a. Is a ceruloplasmin value available:

}	'es		ľ	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 t
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 ___
- 22. A1AT phenotype* (check only one):

MM	(1)
MS	(2)
MZ	(3)
SZ	(4)
ZZ	(5)
Other (specify):	(.)

Iner (specify):	(

specify
Not available (,)

*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*):



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)

*If positive ANA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/____ ____

- **26.** Antismooth muscle antibody (ASMA):

Positive	(* ₁)
Negative	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	27.

*If positive ASMA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/ ____ ___

- 27. Antimitochondrial antibody (AMA):

Positive
Negative
(*1.

Age < 18 and not done

(*2.

28.

(3.

*If positive AMA value, complete either a or b depending on laboratory results:

a. Titer (record only the denominator):

1/____

- **28.** Is patient 18 or older:

(Yes) (No. 2)

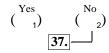
20	Lymphocytotoxic antibody (LCA	١).
49.	• • •	1). (*)
	Positive	(· ₁)
	Negative	(₂)
	Not available	30.
	Not available	(3/
		30.
	*If positive LCA value, comple depending on laboratory results.	ete either a or b
	a. Titer (record only the denomin	nator):
	1/	
	b. Units:	<u> </u>
30.	Antibody to liver-kidney microso antigen (LKM1):	omal
	Positive	(* ₁)
	Negative	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
		31.
	Not available	(
		31.
	*If positive LKM1 value, complete depending on laboratory results.	ete either a or b
	a. Titer (record only the denomin	nator):
	1/	
	b. Units:	<u> </u>
31.	Rheumatoid factor (RF):	
01.	Positive	(*)
	Negative	()
	riogativo	2/
	Not available	(32.)
		32.
	*If positive, record RF value.	<i>52</i> .
	a. Units:	•
	a. UIIIIS.	IU/mL
	If results are given as a titer, re	
	key the actual result in the Gene	rat Comments.

mg/dL
mg/dL
l
year n 5 years prior to ient under age 18;
μО/ПІС
:
n year
ı year
n year

34. IgA:

H. Immunoglobulin levels

32. Are immunoglobulin levels available:



33. Date of blood draw for immunoglobulin levels:

_		_
day	mon	year

Keyed: (

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	9. Weight (shoes off - repeat weight measuremen until you have two measurements within 2 lbs (0.9 kg) of each other):		
1. Center ID:	a. 1st measurement:		
2. Patient ID:	•		
3. Patient code:	b. 2nd measurement:		
	c. Units:		
4. Visit date:	Pounds (,)		
	Kilograms (2)		
day mon year	Trinograms (2)		
5. Visit code: <u>t</u>	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)		
6. Form & revision:pe1	a. 1st measurement:		
7 Study: NAFLD Database 2 6	•		
7. Study: NAFLD Database 2 6	b. 2nd measurement:		
B. Measurements	•		
D. Measurements	c. Units:		
8. Height (shoes off - repeat height measurements	Inches		
until you have two measurements within 0.5 inches (1.3 cm) of each other):	Centimeters (2)		
a. 1st measurement:			
b. 2nd measurement:	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)		
b. Zhu measurement.	a. 1st measurement:		
c. Units:			
	b. 2nd measurement:		
Inches (1) Centimeters (2)	•		
(2)			
	c. Units:		
, 2	c. Units: Inches		

12.	Temperature (oral or other as age):	appropriate	for	D. Liver signs		
				18. Focused liver signs (check all that apply)		
	a. Degrees:			a. None:	(1)
	b. Scale:			b. Jaundice:	(1)
	Fahrenheit:	(1)	c. Palmar erythema:	(1)
	Centigrade:	(2)	d. Contractures:	(1)
13.	Blood pressure			e. Pedal edema:	(1)
	•			f. Spider angiomata:	(1)
	a. Systolic:			g. Asterixis:	(1)
		S		h. Hepatic encephalopathy:	(1)
	b. Diastolic:	mmHg		i. Other, (specify):	(1)
		mmig		, (1 33)		12
14.	Resting radial pulse:	beats/minute		specify		
15.	Respiratory rate:			E. Tanner Staging		
		breaths/m	iinute	19. Is Tanner staging required for this patient		
C. E	Examination findings			(Note: Required during screening if		
16.	Areas with acanthosis nigricans (check all that apply):			patient is 17 years old or younger.) (checone):	ek o	nly
	a. None:	(1)	Yes, patient has not reached full sexual maturity and is 17 years old or younger:	(1)
	b. Neck:	(1)	No, patient is 18 years old or older	(2)
	c. Axilla:	(1)	27	. `	
	d. Elbows:	(1)	No, participant had reached full sexual	_	
	e. Knees:	(1)	maturity (Tanner stage 5 on all parameters at screening or for 2	,	
	f. Knuckles:	(1)	consecutive visits)	(3)
	g. Periumbilical:	(27		_
	g. renumonicai.	(1)	20. Is the patient female:		
17.	Abdomen abnormalities present <i>(check all that apply):</i>			$\binom{\operatorname{Yes}}{1}$	(N	No 2)
	a. None:	(1)	23.		
	b. Ascites:	(1)	Male Tanner Staging		
	c. Obese:	(1)	Trans Turney Sugard		
	d. Splenomegaly:	(1)	21. Genital stage:		5
	e. Hepatomegaly:	(1)		1	ر-
	If Yes, span at right midclavici	ılar line:		22. Pubic hair stage:	1	5
				27	٦	J
		cm		21	<u>.</u>	

Female Tanner Staging

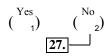
23. Breast stage:

1-5

24. Pubic hair stage:

1-5

25. Has menarche occurred:



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

age in years

F. Administrative information

- **27.** Study Physician PIN:
- **28.** Study Physician signature:

29. Clinical Coordinator PIN:

30. Clinical Coordinator signature:

31. Date form reviewed:

day mon year

NAFLD Database 2

RG - Registration

Purpose: To register patients as candidates for enrollment in the NAFLD Database 2 study and to assign a patient
ID number. This is the first form completed for a NAFLD Database 2 patient. The Registration Form must be
the first form keyed, before any other NAFLD Database 2 forms.
When. At first screening visit (t0)

When: At first screening visit (t0). Administered by: Clinical Coordinator.

Respondent: Patient and parent (if patient is age 17 or younger).

Instructions: Use Flash Cards as instructed. Do not assign an ID if patient has previously been assigned an ID for a NASH CRN study.

•						
A. Center, patient and vi	sit identification	12. Ethnic category (show the patient/parent Flash Card #1 and ask the respondent to pick the category that describes the patient best; check only				
1. Center ID:		one):	песк опіу			
2 Dations ID:		Hispanic or Latino or Latina	(1)			
2. Patient ID:		Not Hispanic, not Latino, not Latina	(2)			
3. Patient code:			14.			
4. Visit date: day	mon year	13. What describes your Hispanic, Latino, or Latina origin best (show the patient/par Card #1 and ask the respondent to pick category that best describes their Hispino, or Latina origin; check only one):	ent Flash k the sub-			
5. Visit code:	t 0	Mexican	(1)			
5. Visit code.	<u> </u>	Puerto Rican	(2)			
6. Form & revision:	<u>r g 1</u>	Cuban	$\begin{pmatrix} & & \\ & & \end{pmatrix}$			
	 	South or Central American	(4)			
7. Study: NA	AFLD Database 2 <u>6</u>	Other Spanish culture or origin	(5)			
B. Consent		specify				
8. Has the patient (or pa signed the NAFLD D consent statement:	atabase 2 informed	14. Racial category (show the patient/parent Flash Card #2 and ask the respondent to pick the category or categories that describe the patient best; check all that apply)				
	$\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$	a. American Indian or Alaska Native:	(1)			
	STOP	b. Asian:	(1)			
C. Information about pa	tient	c. Black, African American, Negro, or Haitian:	(1)			
9. Date of birth:		d. Native Hawaiian or other Pacific Islander:	(1)			
day month		e. White:	(1)			
Record 4-digit year	for date of birth.	f. Patient refused:	(1)			
10. Age at last birthday:	years	15. In what country was the patient born (cone):	heck only			
11. Gender:		Continental US (includes Alaska) or	()			
Male	()	Hawaii	(₁)			
Female	(₁)	Other, (specify):	(2)			
1 Ciliaic	(2)	specify				
		Specif				

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):			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;		
	Never attended school	(0	check only one):	icome besi,
	Kindergarten, pre kindergarten, or	(,	Less than \$15,000	(1)
	younger	(1)	\$15,000 - \$29,999	
	Grades 1 to 5	(2)	\$30,000 - \$49,999	(2)
	Grades 6-8	(3)	\$50,000 or more	()
	Grades 9-11	(4)	400,000 00 00000	4/
	Completed high school	(₅)	D. Previous registration in a NASH CRN	study
	Some college or post high school	(`		
	education or training	(6)	23. Has the patient ever been assigned an number in a NASH CRN study:	ID
	Bachelor's degree or higher	(₇)		No
17.	Is the patient currently employed:			$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$	(2)
	Yes	_ [No		27.
	(1)	(2)	44 Y. 111 Y. 127 GD. Y. 11 1	
18	What is the patient's current occupation	20.		24. In which NASH CRN studies has the patient previously been registered (<i>ch apply</i>)	eck all tha
10.	what is the patient scurrent occupation	.•		a. Database:	(1)
	specify occupation			b. PIVENS:	
	specify occupation				(1)
19.	About how many hours does the patient			c. TONIC:	
	work each week:			d. Other, (specify):	(1)
		# hour	rs		
20.	Which of the following categories best		specify		
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):			25. ID Number previously assigned to patient (record patient ID in item 2):		
	Never employed	(0		•
	Laborer	(1)	26. Code previously assigned to patient (<i>n tient code in item 3</i>):	ecord pa-
	Clerical	(2)		
	Professional	(3)		
	Homemaker	(4)		28.
	Other, (specify):	(₅)	T. T.	
	canal, (specify).	`	5/	F. ID assignment	action R the
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):			 (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. 		
	Married or living in marriage-like				
	relationship	(2)	CCCC ####, zzz	
	Separated, divorced, or annulled	(3)		.
	Widowed	(4)		

Patient ID:		

G. Administrative information

28. Clinical Coordinator PIN: ____ ___

29. Clinical Coordinator signature:

30. Date form reviewed:

day mon year