A

AD – Alcohol Use Disorders Identification Test (AUDIT)

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

When: Visit s1.

Administered by: Self-administered (age 13 or older), interviewer administered (age 8-12). Clinical Coordinator must be available at visits to answer questions and review completed forms.

Respondent: Patient, age 8 or older. Patients age 13 or older should complete the form without help from spouse or family. Clinical Coordinator/parent can assist patients age 8-12.

Instructions: Flash Card #15, Drink Equivalents, may be used with this form. The Clinical Coordinator should complete section A below and write the patient ID on pages 2-3. If the form is self-administered by the patient, the patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator then should complete section B below.

. Ce	enter, patient, and vis	sit identification		Administrative information (To be completed by Clinical Coordinator after	
1.	Center ID:			survey is completed.)	
2.	Patient ID:		8.	3. How was the questionnaire completed:	
3.	Patient code:			Self-administered by patient (1)
4.	Date of visit (date po	atient completed the form):		10.	
	day	mon year			2) 3)
5.	Visit code:	<u>s</u> <u>1</u>	9.	0. Who was the respondent <i>(check all that apply)</i> :	
6.	Form & revision:	<u>a</u> <u>d</u> <u>1</u>		b . Patient's mother or female guardian: (1)
7.	Study:	NAFLD Database <u>1</u>			1) 1)
				specify	_
			10.	a. PIN:b. Signature:	_
			11.	Date form reviewed:	_
				day mon year	_

AD – Alcohol Use Disorders Identification Test (AUDIT)

Instructions: This survey asks for your views about your alcohol use. Please check one for each question below (*items 1-11 are for clinical center use only*).

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

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

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

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

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

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

15. 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
$\begin{pmatrix} 0 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(4)

16. 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
$\begin{pmatrix} 0 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 4 \end{pmatrix}$

Patient ID:		

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

	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 had a feeling of guilt or remorse after drinking?

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

19. 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
(0)	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(4)

20. 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
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(₁)	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

21. 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
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	(1)	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

22. Today's date:

Thank you for completing this questionnaire.

BG - Baseline History

Purpose: To collect baseline history information about the patient.

When: Visit s1.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient or patient's parent.

Instructions: Collect information by interview or chart review. If c is checked for an item, use caution. If the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database. If is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database. The form should not be keyed to the data system, but the form should be retained; set aside with forms for other patients who started screening, but were found to be ineligible.

Α.	Center.	visit.	and	patient	identification

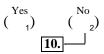
- **1.** Center ID: ____ ___ ___
- **2.** Patient ID: ____ __ ___
- 3. Patient code:
- **4.** Visit date (date this form is initiated):

_		_
day	mon	year

- **5.** Visit code: <u>s 1 ____</u>
- **6.** Form & revision: <u>b g 3</u>
- 7. Study: NAFLD Database 1

B. Family history

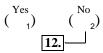
8. Do any of the patient's first degree relatives (parent, brother, sister, child) have liver disease:



- **9.** If yes, characterize the liver disease(s) (*check all that apply*)
 - **a.** Alcohol related liver disease: (1)
 - **b.** Viral hepatitis: (₁)
 - **c.** Alpha-1 antitrypsin deficiency:
 - **d.** Wilson's disease:
 - e. Glycogen storage disease: (1)
 - **f.** Iron overload: (,)
 - **g.** Fatty liver disease (*NAFLD*, *NASH*):
 - **h.** Primary liver cancer: (₁)
 - i. Type of liver disease unknown: (1)
 - **j.** Other (specify):

specify

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



11. If yes, is the cause of the cirrhosis unknown (cryptogenic):

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

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

13.	Do any of the patient's first degree relatives (parent, brother, sister, child) have obesity:		
	Yes	(1)
	No	(1) 2) 2)
	Don't know	(3)
14.	Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat:		
	Yes	(1)
	No	(1) 2)
	Don't know	(3)
15.	Do any of the patient's first degree relatives (parent, brother, sister, child) have a problem with cholesterol or blood fat:		
	Yes	(1)
	No	(2)
	Don't know	(3)

C.	NAFLD	history
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16. Date patient was first diagnosed with fatty liver disease or cryptogenic cirrhosis:

<u>=</u>		
day	mon	year

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

a. Symptoms for liver disease:	(1)
b. Result of being evaluated for another		

illness:	(1
c. During a routine or insurance physical		
examination:	(1)

d. Blood donation:	(1
e. Other (<i>specify</i>):	(1

-	specify

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

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

specify

19. Does the patient have one or more liver biopsies done prior to registration in the Database that you want evaluated for the

Database:

Yes		1	No
(1)	(2)
	2	21.	J

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

day	mon	year

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



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

		<u> </u>
day	mon	year

21. Will the patient have a biopsy during screening:

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

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

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



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

D. Weight history

23. What was the patient's birthweight:

	_
lbs	oz

24. *Review flashcard 17.* Which (picture) best describes your weight pattern over the past 5 years (*check only one*):

Up and down, up and down	(1
Up gradually	(2
Up sharply (gained a lot in a brief interva	<i>l)</i> (3
Down gradually	(4
Down sharply (lost a lot in a brief interval	l) (5
No or minimal change	(6.

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

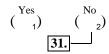
26.	What is the most the patient has ever weighed:		
		lbs	

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

age in	years

lbs

28. Is the patient age 18 or older:



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

	lbs	

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

age in	years

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



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

lbs	
108	

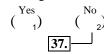
33. Does the patient weigh less than he/she did one year ago:



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

lbs	

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



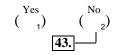
36. Which did the patient try to do (*check only one*):

Gain weight	(1)
Lose weight	(2)

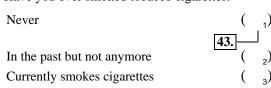
E. Tobacco cigarette smoking history

(interview with patient; not interview with parent, not by chart review)

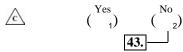
37. Is the patient age 8 or older:



38. Have you ever smoked tobacco cigarettes:



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):



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 you didn't stop smoking):

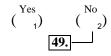
years

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

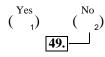
garettes/day
igai ettes/uay

F. Menstrual history

43. Is the patient female:



44. Has menarche occurred:



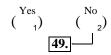
45. What was the patient's age at menarche:

age in years

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

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

47. Is patient post-menopausal:



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

age in years

- **G. Medical history** (means Caution; condition is exclusionary if study physician agrees with diagnosis)
- **49.** Has the patient ever been diagnosed with and treated for any of the following (*check all that apply; source of information can be interview and/or chart review*)

a. Diabetes type 1:	(1)
b. Diabetes type 2:	(1)
c. Gestational diabetes (diabetes of pregnancy):	(1)
d. Henatitis B:	(.)

Hepatitis B:

e. Hepatitis C:	(1)	af. Hypertension:	(1)
	<u></u>	ag. Cerebrovascular disease:	(1)
f. Autoimmune hepatitis:	(1)	ah. Dysbetalipoproteinemia:	_(1)
g. Autoimmune cholestatic liver disc	order	<u>/c</u>	7—	
(PBC or PSC):	<u>(</u>	ai. Hyperlipidemia (high cholesterol, high triglycerides):	(1)
h. Wilson's disease:	(1)	aj. Pancreatitis:	(1)
	<u>c</u>	ak. Cholelithiasis:	(1)
i. Alpha-1-antitrypsin (A1AT) defic	iency: (1)	al. Coronary artery disease:	(1)
	<u></u>	am. Elevated uric acid such as gout:	(1)
j. Iron overload:	(1)	an. Kidney disease:	(1)
	<u></u>	ao. Polycystic ovary syndrome:	(1)
k. Drug induced liver disease:	(1)	ap. Sleep apnea (not breathing	,	`
l. Gilbert's syndrome:	(1)	during sleep):	(1)
m. Esophageal or gastric varices on	()	aq. Dermatologic disorders:	(1)
endoscopy:	(1)	ar. Myopathy:	(1)
n. Bleeding from varices:	(1)	as. Myositis:	(1)
o. Other gastrointestinal bleeding:	(1)	at. Major depression:	(1)
p. Ascites:	(1)	au. Schizophrenia:	(1)
q. Edema:	(1)	av. Bipolar disorder:	(1)
r. Hepatic encephalopathy:	(1)	aw. Obsessive compulsive disorder:	(1)
s. Portal hypertension:	(1)	ax. Severe anxiety or personality disorder:	()
t. Hepatorenal syndrome:	(1)		(1)
u. Hepatopulmonary syndrome:	(1)	ay. None of the above:	(1)
v. Short bowel syndrome:	(50. Has the patient ever had surgery for any of the following (<i>check all that apply</i>)		
w. Hemophilia (bleeding disorder):	(₁)	a. Stapling or banding of the stomach:	7—	₁)
x. Systemic autoimmune disorder su rheumatoid arthritis or systemic lu		b. Jejunoileal (or other intestinal) bypass:	(1)
y. Endocrine disease (hormonal abnormality):	(₁)	c. Biliopancreatic diversion:	7—	_ ₁)
z. Hepatocellular carcinoma:	(1)	d Other CL or heriotric gurgery (areasity)	7—]
aa. Other malignancy (cancer):	()	d. Other GI or bariatric surgery (<i>specify</i>):	(₁)
ab. Peripheral neuropathy:	()			
ac. Seizure disorder or epilepsy:	()	e. None of the above:	(1)
	(₁)			
ad. Drug allergies:	(₁)			

ae. Hypothyroidism:

(1)

51. Organ, limb, or bone marrow transplant a. Has the patient ever received a liver			55. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 6 months (<i>check all that apply</i>):		
transplant:	N	Jo	a. Chlordiazepoxide (Librium):	(1)
	ر (`` الم	2)	b. Clorazepate dipotassium (Tranxene):	(1) 1)
<u> </u>	3)		c. Diazepam (Valium):	(1) 1)
b. Has the patient ever received any			d. Disulfiram (Antabuse):	(1)
other organ, limb, or bone marrow transplant:			e. Hydroxyzine pamoate (Vistaril):	(1) 1)
$\begin{pmatrix} \text{Yes} \\ \begin{pmatrix} 1 \end{pmatrix} \end{pmatrix}$	(N	No 2)	f. Naltrexone hydrochloride (Revia):	(1)
	(2/	·	(1) 1)
52. Has the patient received total parenteral nutrition (TPN) in the past 2 years:		т_	g. Other, (specify):		1)
$\binom{\operatorname{Yes}}{1}$	(√o 2)	h. None of the above:	(1)
53. Is the patient currently undergoing evaluation for bariatric surgery: Yes	(N	√o _2)	56. Has the patient taken any antihyperlipidemic medications in the past 6 months (<i>check all that apply</i>):		
(1)	(2)	a. Atorvastatin (Lipitor):	(1)
H. Medication use			b. Colestipol hydrochloride (Colestid):	(1)
54. Has the patient used any antidiabetic medications in the past 6 months			c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate):	(1)
(check all that apply):			d. Gemfibrozil (Gen-Fibro, Lopid):	(1)
a. Acarbose (Precose):	(1)	e. Fenofibrate (Tricor):	(1)
b. Acetohexamide (Dymelor):	(1)	f. Fluvastatin sodium (Lescol):	(1)
c. Chlorpropamide (Diabinese):	(1)	g. Lovastatin (Mevacor):	(1)
d. Glimepiride (Amaryl):	(1)	h. Nicotinic acid (Niaspan):	(1)
e. Glipizide (Glucotrol, Glucatrol XL):	(1)	i. Pravastatin sodium (Pravachol):	(1)
f. Glyburide (Micronase, DiaBeta, Glynase):	(`	j. Rosuvastatin (Crestor):	(1)
g. Insulin:	(1)	k. Simvastatin (Zocor):	(1)
	(1)	l. Other, (specify):	(1)
h. Metformin (Glucophage, Glucophage XR):	(1)			
i. Miglitol (Glycet):	(1)	m. None of the above:	(1)
j. Nateglinide (Starlix):	(1)		`	17
k. Pioglitazone (Actos):	(1)			
l. Repaglinide (Prandin):	(1)			
m. Rosiglitazone (Avandia):	(1)			
n. Tolazamide (Tolinase):	(1)			
o. Tolbutamide (Orinase):	(1)			
p. Other, (specify):	(1)			

q. None of the above:

57.	Has the patient taken any antiobesity medications in the past 6 months (check all that apply):			59. Has the patient taken any strong opiates containing acetaminophen medication in the past 6 months (<i>check all that apply</i>)		
	a. Dexfenfluramine hydrochloride			a. Darvocet:	(1)
	(Redux):	(1)	b. Esgic - Plus:	(1)
	b. Fenfluramine hydrochloride (Pondimin):	(1)	c. Fioricet:	(1)
	c. Methamphetamine hydrochloride	`	12	d. Lorcet:	(1)
	(Desoxyn, Gradumet):	(1)	e. Lortab:	(1)
	d. Orlistat (Xenical):	(1)	f. Norco:	(1)
	e. Phendimetrazine tartrate (Adipost, Bontril):	(1)	g. Percocet:	(1)
	f. Phentermine hydrochloride (Adipex,	(1/	h. Talacen:	(1)
	Fastin, Ionamin, Teramine):	(1)	i. Tylenol #3:	(1)
	g. Sibutramine hydrochloride			j. Tylenol #4:	(1)
	monohydrate (Meridia):	(1)	k. Tylox:	(1)
	h. Other, (specify):	(1)	l. Vicodin:	(1)
				m. Wygesic:	(1)
	i. Other, (specify):	(1)	n. Other, (specify):	(1)
	j. None of the above:	(1)	o. None of the above:	(1)
58.	Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 6 months (check all that apply):			60. Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications in the past 6 months (<i>check a hat apply</i>):	11	
	a. Acetaminophen (Tylenol):	(1)	a. Cimetidine (Tagamet):	(1)
			1/		(
	b. Aspirin - 325 mg:	(b. Esomeprazole magnesium (Nexium):	(1)
	b. Aspirin - 325 mg: c. Aspirin - 81 mg:	(1)	b. Esomeprazole magnesium (Nexium):c. Famotidine (Pepcid):	(1)
		((1) 1)		((1)
	c. Aspirin - 81 mg:	((((1) 1) 1)	c. Famotidine (Pepcid):	((((1) 1)
	c. Aspirin - 81 mg:d. Celecoxib (Celebrex):	((((((((((((((((((((1) 1) 1) 1)	c. Famotidine (Pepcid):d. Lansoprazole (Prevacid):	((((((((((((((((((((1) 1) 1)
	c. Aspirin - 81 mg:d. Celecoxib (Celebrex):e. Ibuprofen (Advil, Motrin):	((((((((((((((((((((1) 1) 1) 1) 1) 1)	c. Famotidine (Pepcid):d. Lansoprazole (Prevacid):e. Nizatidine (Axid):	((((((((((((((((((((1) 1) 1)
	 c. Aspirin - 81 mg: d. Celecoxib (Celebrex): e. Ibuprofen (Advil, Motrin): f. Indomethacin (Indocin): 	((((((((((((((((((((1) 1) 1) 1) 1) 1) 1) 1)	c. Famotidine (Pepcid):d. Lansoprazole (Prevacid):e. Nizatidine (Axid):f. Omeprazole (Prilosec):		1) 1) 1) 1) 1) 1)
	 c. Aspirin - 81 mg: d. Celecoxib (Celebrex): e. Ibuprofen (Advil, Motrin): f. Indomethacin (Indocin): g. Naproxen (Aleve, Naprosyn): 		1) 1) 1) 1) 1) 1)	 c. Famotidine (Pepcid): d. Lansoprazole (Prevacid): e. Nizatidine (Axid): f. Omeprazole (Prilosec): g. Ranitidine (Zantac): 		1) 1) 1) 1) 1) 1) 1) 1)
	 c. Aspirin - 81 mg: d. Celecoxib (Celebrex): e. Ibuprofen (Advil, Motrin): f. Indomethacin (Indocin): g. Naproxen (Aleve, Naprosyn): h. Rofecoxib (Vioxx): 		1) 1) 1) 1) 1) 1) 1) 1) 1) 1)	 c. Famotidine (Pepcid): d. Lansoprazole (Prevacid): e. Nizatidine (Axid): f. Omeprazole (Prilosec): g. Ranitidine (Zantac): h. Ranitidine bismuth citrate (Tritec): 		1) 1) 1) 1) 1) 1) 1) 1) 1) 1)
	 c. Aspirin - 81 mg: d. Celecoxib (Celebrex): e. Ibuprofen (Advil, Motrin): f. Indomethacin (Indocin): g. Naproxen (Aleve, Naprosyn): h. Rofecoxib (Vioxx): i. Other, (specify): 	(1) 1) 1) 1) 1) 1) 1) 1) 1) 1) 1)	 c. Famotidine (Pepcid): d. Lansoprazole (Prevacid): e. Nizatidine (Axid): f. Omeprazole (Prilosec): g. Ranitidine (Zantac): h. Ranitidine bismuth citrate (Tritec): i. Antacids, (specify): 		1) 1) 1) 1) 1) 1) 1) 1) 1) 1)

61.	Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months (check all that apply):			63. Has the patient taken any cardiovascular or antihypertensive medications in the past 6 months (<i>check all that apply</i>):		
	a. Clopidogrel (Plavix):	(1)	a. Amiodarone (Pacerone):	(1)
	b. Dipyridamole:	(1)	b. Amlodipine besylate (Norvasc):	(1)
	c. Heparin:	(1)	c. Atenolol (Tenormin):	(1)
	d. Ticlopide (Ticlid):	(1)	d. Benazepril (Lotensin):	(1)
	e. Warfarin (Coumadin):	(1)	e. Captopril (Capoten):	(1)
	f. Other, (specify):	(1)	f. Clonidine (Catapres):	(1)
				g. Digoxin (Lanoxin):	(1)
	g. Other, (specify):	(1)	h. Diltiazem (Cardizem):	(1)
				i. Doxazosin (Cardura):	(1)
	h. None of the above:	(1)	j. Enalapril (Vasotec):	(1)
		`	17	k. Felodipine (Plendil):	(1)
62.	Has the patient taken any systemic corticosteroids in the past 6 months			l. Furosemide (Lasix):	(1)
	(check all that apply):			m. Hydrochlorothiazide (Esidrix,		
	a. Betamethasone sodium (Celestone):	(1)	HydroDIURIL):	(1)
	b. Cortisol:	(1)	n. Hydrochlorothiazide + triamterene(Dyazide):	(1)
	c. Cortisone:	(1)	o. Lisinopril (Prinivil, Zestril):	(1) 1)
	d. Dexamethasone (Decadron):	(1)	p. Losartan potassium (Cozaar):	(1)
	e. Hydrocortisone (Hydrocortone):	(1)	q. Losartan potassium with		1/
	f. Methylprednisolone (Solu-Medrol):	(1)	hydrochlorothiazide (Hyzaar):	(1)
	g. Prednisolone (Prelone):	(1)	r. Metoprolol (Lopressor):	(1)
	h. Prednisone:	(1)	s. Nifedipine (Adalat, Procardia):	(1)
	i. Triamcinolone (Acetocot, Amcort,			t. Perhexiline maleate:	(1)
	Aristocort, Kenacort):	(1)	u. Propranolol (Inderal):	(1)
	j. Other, (specify):	(1)	v. Quinapril (Accupril):	(1)
				w. Terazosin (Hytrin):	(1)
	k. Other, (specify):	(1)	x. Timolol maleate (Blocadren):	(1)
				y. Valsartan (Diovan):	(1)
	l. None of the above:	(1)	z. Verapamil (Calan):	(1)
				aa. Other, (specify):	(1)
				ah Other (spacify):	(
				ab. Other, (specify):	(

(1)

ac. None of the above:

• Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months (check all that apply):						
a. Conjugated estrogen (Premarin/Prempro):	(1)				
b. Diethylstilbestrol and methyltestosterone (Tylosterone):	(1)				
c. Esterified estrogen (Estratab, Menest):						
d. Estradiol (Estrace):	(1)				
e. Ethinyl estradiol (Estinyl):	(1)				
f. Fluoxymesterone (Android-F, Halotestin):	(1)				
g. Levonorgestrel (Norplant):	(1)				
h. Medroxyprogesterone (Cycrin, Provera):	(1)				
i. Megestrol (Megace):	(1)				
j. Methyltestosterone (Android):	(1)				
k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin):	(₁)				
l. Norethindrone (Micronor):	(1)				
m. Norgestrel (Ovrette):	(1)				
n. Oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia):	(1)				
o. Oxandrolone (Oxandrin):	(1)				
p. Oxymetholone (Anadrol):	(1)				
q. Progesterone (Prometrium):	(1)				
r. Raloxifene (Evista):	(1)				
s. Tamoxifen (Nolvadex):	(1)				
t. Other, (specify):	(1)				
u. Other, (specify):	(1)				
v. None of the above:	(1)				

65. Has the patient taken any allergy or asthma medications in the past 6 more (check all that apply):	nths	
a. Albuterol:	(1)
b. Beclomethasone dipropionate (Beclovent, Vanceril):	(1)
c. Budesonide (Pulmicort, Rhinocort	t): (1)
d. Fluticasone propionate (Flonase, Flovent):	(1)
e. Loratadine (Claritin):	(1)
f. Mometasone furoate (Nasonex):	(1)
g. Triamcinolone acetonide (Azmaco Nasacort):	ort,	1)
h. Other, (specify):	(1)
i. Other, (specify):	(1)
j. None of the above:	(1)
66. Has the patient taken a multivitamin	(1)
-	`	No 2)
66. Has the patient taken a multivitamin regularly in the past 6 months:) (17
66. Has the patient taken a multivitamin regularly in the past 6 months:Yes (1)67. Has the patient taken vitamins other multivitamins in the past 6 months:) (17
66. Has the patient taken a multivitamin regularly in the past 6 months: Yes Yes 1) (than	17
 66. Has the patient taken a multivitamin regularly in the past 6 months: Yes (1) 67. Has the patient taken vitamins other multivitamins in the past 6 months: 	than (69.	17
66. Has the patient taken a multivitamin regularly in the past 6 months: (Yes (10) 67. Has the patient taken vitamins other multivitamins in the past 6 months: (Yes (10) 68. Which vitamins has the patient taken	than (69.	17
66. Has the patient taken a multivitamin regularly in the past 6 months: Yes Yes Yes Yes Yes Yes Yes Y	than (69.	No 2)
 66. Has the patient taken a multivitamin regularly in the past 6 months: Yes Yes Yes Yes Yes Yes Yes Y	() (than () (69.	No 2)
 66. Has the patient taken a multivitamin regularly in the past 6 months: Yes Yes Yes Yes Yes Yes Yes Y	() (than () () () () () () () () () () () () ()	No 2)

1)

• Has the patient taken any supplements in the past 6 months (<i>check all that apply</i>):			70. Has patient taken any of the following medications or other
a. Alpha-lipoic acid:	(1)	supplements/medications in the past 6 months (record all other
b. Alpha-tocopherol:	(1)	supplements/medications):
c. Beta-carotene:	(1)	a. Demeclocycline (Declomycin):
d. Betaine (Cystadane):	(1)	b. Divalproex (Depakote):
e. Calcium (any form):	(1)	c. Doxycycline (Monodox):
f. Carnitine (any form):	(1)	d. Isotretinoin (Accutane):
g. Chondroitin (any form):	(1)	e. Levothyroxine (Levoxyl, Synthroid):
h. Choline + methionine + betaine +			f. Liothyronine (Cytomel):
adenosine + pyridoxine (Epocler):	(1)	g. Methotrexate (Rheumatrex):
i. Cod liver oil:	(1)	h. Minocycline (Dynacin, Minocin):
j. Coenzyme Q:	(1)	i. Oxytetracycline (Terramycin):
k. Dichloroacetate:	(1)	j. Penicillamine (Cuprimine, Depen):
l. Echinacea:	(1)	k. Tetracycline (Achromycin):
m. Fish oil (any form):	(1)	l. Trientine hydrochloride (Syprine):
n. Flax seed oil:	(1)	m. Ursodeoxycholic acid (Actigall, Urso,
o. Garlic:	(1)	Ursodiol):
p. Ginkgo biloba:	(1)	n. Valproate sodium (Depacon):
q. Glucosamine (any form):	(1)	o. Valproic acid (Depakene):
r. Lecithin:	(1)	p. Other, (specify):
s. Magnesium:	(1)	
t. Milk thistle:	(1)	q. Other, (specify):
u. N-acetyl-cysteine:	(1)	
v. Potassium (any form):	(1)	r. Other, (specify):
w. S-adenylmethionine (SAM-e):	(1)	
x. Saw palmetto:	(1)	s. Other, (specify):
y. Selenium:	(1)	
z. St. John's Wort:	(1)	t. Other, (specify):
aa. Taurine:	(1)	· Outer, (speegy).
ab. Zinc picolinate:	(1)	u. None of the above:
ac. Other, (specify):	(1)	u. None of the above:
ad. Other, (specify):	(1)	
ae. None of the above:	(

I. Administrative information
71. Study Physician PIN:
72. Study Physician signature:
73. Clinical Coordinator PIN:
74. Clinical Coordinator signature:
75. Date form reviewed:

mon

year

day

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.

	1. Center ID
	2. Patient ID
<u> </u>	3. Patient code
///	4. Date of central reading
	5. Visit code
<u>c r 1</u>	6. Form and revision
_	7. Study: 1 =Database; 2 =PIVENS; 3 =TONIC
//	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
	d. Other slide
	Specify type of stain for other slide
	C. Administrative information 10. CC Initials
	11. CC Signature
///	12. Date form reviewed
_	13. Tissue adequate: 0 =No → Request original slides from submitting clinic; 1 =Yes
	14. Followup with clinic (Specify):

Patient ID D. Histology
15. Biopsy length (mm)
H & E stain
16. Steatosis (assume macro, e.g., large and small droplet)
a. Grade: 0 =<5%; 1 =5-33%; 2 =34-66%; 3 =>66%
b. Location: 0 =Zone 3 (<i>central</i>); 1 =Zone 1 (<i>periportal</i>); 2 =Azonal; 3 =Panacinar
c. Microvesicular steatosis, contiguous patches: 0 =Absent; 1 =Present
17. Inflammation
a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci:
0 =0; 1 =<2 under 20x mag; 2 =2-4 under 20 mag; 3 =>4 under 20 mag
b. Microgranulomas seen: 0 =No; 1 =Yes
c. Large lipogranulomas seen: 0=No; 1=Yes
d. Amount of portal, chronic inflammation: 0 =None; 1 =Mild; 2 =More than mild
18. Liver cell injury
a. Ballooning: 0 =None; 1 =Few; 2 =Many
b. Acidophil bodies: 0 =Rare/absent; 1 =Many
c. Pigmented macrophages (<i>Kupffer cells</i>): 0 =Rare/absent; 1 =Many
d. Megamitochondria: 0 =Rare/absent; 1 =Many
<u> </u>
19. Mallory's hyaline: 0 =Rare/absent; 1 =Many
20. Glycogen nuclei: 0 =Rare/absent; 1 =Many
Masson's trichrome stain
21. Fibrosis stage: 0 =None; 1a =Mild, zone 3 perisinusoidal (<i>requires trichrome</i>);
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
22. Iron stain
a. Hepatocellular iron grade: 0 =Absent or barely discernible, $40x \rightarrow GOTO$ item 22c; 1 =Barely discernable granules, $20x$; 2 =Discrete granules resolved, $10x$; 3 =Discrete granules resolved, $4x$;
4=Masses visible by naked eye
b. Hepatocellular iron distribution: 0 =Periportal; 1 =Periportal and midzonal; 2 =Panacinar; 3 =Zone 3 or azonal
c. Nonhepatocellular iron grade: 0=None → GOTO item 23; 1=Mild; 2=More than mild
d. Nonhepatocellular iron distribution: 0 =Large vessel endothelium only; 1 =Portal/fibrosis bands only, but mor
than just in large vessel endothelium; 2=Intraparenchymal only; 3=Both portal and intraparenchymal
23. Is this steatohepatitis? 0 =No; 1a =Suspicious/borderline/indeterminate: Zone 3 pattern;
1b =Suspicious/borderline/indeterminate: Zone 1, periportal pattern; 2 =Yes, definite
24. Is cirrhosis present? 0 =No → GOTO item 27 ; 1 =Yes
25. Is this cryptogenic cirrhosis: 0 =No → GOTO item 27 ; 1 =Yes
26. Features suggestive of steatohepatitis etiology for cryptogenic cirrhosis:
 a. Mallory's hyaline (<i>rule out cholate stasis</i>): 0 =Absent; 1 =Present
b. Perisinusoidal fibrosis away from septa: 0 =Absent; 1 =Present
c. Hepatocyte ballooning: 0 =Absent; 1 =Present
d. Megamitochondria: 0 =Absent; 1 =Present
e. Other notable findings: 0 =Absent; 1 =Present; Specify:
27. Other comments:

DR - Death Report

Purpose: To record the report of a patient's death.

When: As soon as clinic is notified of a patient's death.

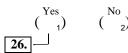
Administered by: Study Physician and Clinical Coordinator.

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

A. Center, patient, and visit identifica	tion	10. Place of death:				
1. Center ID:		city/state/country				
2. Patient ID:			city/state/country			
3. Patient code:4. Date form is initiated (date of notice)	— — — e):	11. Cause of death (Study Physician: use whatever knowledge y have and your best medical judgment to best ch acterize the cause of death; check only one):				
day mon			Heart disease	(1)		
•	your		Stroke	(2)		
5. Visit code:n			Liver disease	$\begin{pmatrix} & 3 \end{pmatrix}$		
		1	Malignancy	(4)		
6. Form & revision:d	<u> </u>	1	Other (specify):	$\begin{pmatrix} & & \\ & & 5 \end{pmatrix}$		
7. Study: NAFLD D	atabase_	1	specify			
B. Death information			specify			
8. Date of death:			Unknown	(6)		
day mon	year		C. Administrative information			
9. Source of death report (check all the	at apply):		12. Study Physician PIN:			
a. Patient's family:	(1)				
b. Friend:	(1)	13. Study Physician signature:			
c. Health care provider or NASH C staff:	RN (1)	14. Clinical Coordinator PIN:			
d. Newspaper:	(1)				
e. Funeral parlor/home:	(1)	15. Clinical Coordinator signature:			
f. Medical record:	(1)				
g. Medical examiner:	(1)	16. Date form reviewed:			
h. Coroner:	(1)				
i. Other (specify):	(1)	day mon	year		
other source						
other source						

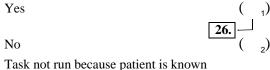
F. Eligibility check

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



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

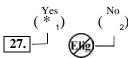
24. Were any STOP's or ineligible conditions other than "missing Form ED" identified by the Enrollment Task:



to be ineligible

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

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



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

G. Reasons for ineligibility for ineligible patients

NOTE: Complete this section for ineligible patients only.

- **26.** Reason for ineligibility (check all that apply)
 - **a.** Reason covered in items 8-14, 22, or 25:
 - **b.** Tests are outside time window and clinic chose not to repeat tests: (1)
 - **c.** Other reason not covered on this form (*specify*):

H. Administrative information

- 27. Study Physician PIN:
- 28. Study Physician signature:
- **29.** Clinical Coordinator PIN: ____ ___
- **30.** Clinical Coordinator signature:
- **31.** Date form reviewed:

day	mon	year

HI - Followup Medical History

Purpose: To record followup medical history information about the patient.

When: f024, f048, f096, f144, and f192.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.

Instructions: Collect information by interview or chart review.

Α.	Center.	visit.	and	patient	identificati	on
7 A.	Cuitti,	41016	anu	paucit	iuciiuiicau	U

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

day	mon	year

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

B. Interval identification

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

day	mon	year

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

C. NAFLD evaluation

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

$$\begin{pmatrix} \text{Yes} \\ * \\ 1 \end{pmatrix} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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

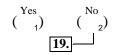
11. Has the patient had an upper abdominal imaging study since the last visit:

$$\begin{pmatrix} \text{Yes} & & & \text{No} \\ (*) & & & & \end{pmatrix}$$

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

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

12. Is the patient age 8 or older:



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

Never	()
	16.
Monthly or less	(
Two to four times a month	(2)
Two to three times a week	(3)
Four or more times a week	(4)

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

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

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	vou smoked			s. Portal hypertension:	(1)
tobacco cigarettes regula	tobacco cigarettes regularly ("No" means smoked less than 1 day per week on avera Yes			t. Hepatorenal syndrome:	(1)
smoked less than 1 day per week on averag		<i>(e):</i> N	lo	u. Hepatopulmonary syndrome:	(1)
		(2)	v. Short bowel syndrome:	(1)
	19.		J	w. Hemophilia (bleeding disorder):	(1)
17. On average, how many week have you smoked				x. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus:	(1)
18. On the days that you sm	oked, about	# 0	lays	y. Endocrine disease (hormonal abnormality):	(1)
• •	how many cigarettes did you smoke			z. Hepatocellular carcinoma:	(1)
per day:				aa. Other malignancy (cancer):	(1)
	# cigarettes]	per d	lay	ab. Peripheral neuropathy:	(1)
F. Medical history				ac. Seizure disorder or epilepsy:	(1)
19. Since the last visit, has t	he natient been			ad. Drug allergies:	(1)
diagnosed with or treate	d for any of the			ae. Hypothyroidism:	(1)
following (check all that tion can be interview ar		fori	na-	af. Hypertension:	(1)
a. Diabetes type 1:	,	(1)	ag. Cerebrovascular disease:	(1)
b. Diabetes type 2:		(1)	ah. Dysbetalipoproteinemia:	(1)
c. Gestational diabetes (diabetes of pregnant	cy):	(1)	ai. Hyperlipidemia (high cholesterol, high triglycerides):	(1)
d. Hepatitis B:		(1)	aj. Pancreatitis:	(1)
e. Hepatitis C:		(1)	ak. Cholelithiasis:	(1)
f. Autoimmune hepatiti	s:	(1)	al. Coronary artery disease:	(1)
g. Autoimmune cholest	atic liver disorder		·	am. Elevated uric acid such as gout:	(1)
(PBC or PSC):		(1)	an. Kidney disease:	(1)
h. Wilson's disease:		(1)	ao. Polycystic ovary syndrome:	(1)
i. Alpha-1-antitrypsin (A1AT) deficiency:	(1)	ap. Sleep apnea (not breathing during sleep):	()
j. Iron overload:		(1)	aq. Dermatologic disorders:	(1) 1)
k. Drug induced liver d	isease:	(1)	ar. Myopathy:	(1)
l. Gilbert's syndrome:		(1)	as. Myositis:	(1)
m. Esophageal or gastri endoscopy:	c varices on	(1)	at. Major depression:	(1)
n. Bleeding from varice	es:	(1)	au. Schizophrenia:	(1)
o. Other gastrointestina	l bleeding:	(1)	av. Bipolar disorder:	(1)
p. Ascites:		(1)	aw. Obsessive compulsive disorder:	(1)
q. Edema:		(1)	ax. Severe anxiety or personality disorder:	(1)
				ay. None of the above:	(1)

20.	Since the last visit, has the patient had surgery for any of the following			G. Medication use		
	(check all that apply)a. Stapling or banding of the stomach:	(1)	26. Since the last visit, has the patient used any antidiabetic medications (<i>check all that apply</i>):		
	b. Jejunoileal (or other intestinal) bypass:	(1)	a. Acarbose (Precose):	(1)
	c. Biliopancreatic diversion:	(1)	b. Acetohexamide (Dymelor):	(1)
	d. Other GI or bariatric surgery (<i>specify</i>):	(1)	c. Chlorpropamide (Diabinese):	(1)
				d. Glimepiride (Amaryl):	(1)
	e. None:	(1)	e. Glipizide (Glucotrol, Glucatrol XL):	(1)
21.	Since the last visit, has the patient received an organ, limb, or bone marrow			f. Glyburide (Micronase, DiaBeta, Glynase):	(1)
	transplant:			g. Insulin:	(1)
	$\binom{\operatorname{Yes}}{1}$	(No 2)	h. Metformin (Glucophage, Glucophage XR):	(1)
22.	Since the last visit, has the patient			i. Miglitol (Glycet):	(1)
	received total parenteral nutrition (TPN): Yes	1	No	j. Nateglinide (Starlix):	(1)
	$\binom{\operatorname{Yes}}{1}$	(No 2	k. Pioglitazone (Actos):	(1)
23.	Is the patient currently undergoing			l. Repaglinide (Prandin):	(1)
	evaluation for bariatric surgery:	N	No.	m. Rosiglitazone (Avandia):	(1)
	$\binom{\operatorname{Yes}}{1}$	(No 2	n. Tolazamide (Tolinase):	(1)
24.	Since the last visit, has the patient been			o. Tolbutamide (Orinase):	(1)
	hospitalized:		. T	p. Other, (specify):	(1)
	$\binom{\mathrm{Yes}}{1}$	(2)			
	If Yes, specify reason:]—	_	q. None of the above:	(1)
	specify reason			27. Since the last visit, has the patient taken any alcohol abuse (dependance or withdrawal) medications (<i>check all that app</i>	oly).	:
25.	Since the last visit, has the patient had			a. Chlordiazepoxide (Librium):	(1)
	any serious health problem not already reported:			b. Clorazepate dipotassium (Tranxene):	(1)
	Yes (Yes	(1	/o /	c. Diazepam (Valium):	(1)
	<u> </u>	\ 		d. Disulfiram (Antabuse):	(1)
	If Yes, specify:	1		e. Hydroxyzine pamoate (Vistaril):	(1)
	specify			f. Naltrexone hydrochloride (Revia):	(1)
	specify			g. Other, (specify):	(1)
				h. None of the above:	(1)

28.	Since the last visit, has the patient taken any antihyperlipidemic medications (check all that apply):			30. Since the last visit, has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing		
	a. Atorvastatin (Lipitor):	(1)	medications (check all that apply):		
	b. Colestipol hydrochloride (Colestid):	(1)	a. Acetaminophen (Tylenol):	(1)
	c. Clofibrate (Abitrate, Atromid-S,		17	b. Aspirin - 325 mg:	(1)
	Claripex, Novofibrate):	(1)	c. Aspirin - 81 mg:	(1)
	d. Gemfibrozil (Gen-Fibro, Lopid):	(1)	d. Celecoxib (Celebrex):	(1)
	e. Fenofibrate (Tricor):	(1)	e. Ibuprofen (Advil, Motrin):	(1)
	f. Fluvastatin sodium (Lescol):	(1)	f. Indomethacin (Indocin):	(1)
	g. Lovastatin (Mevacor):	(1)	g. Naproxen (Aleve, Naprosyn):	(1)
	h. Nicotinic acid (Niaspan):	(1)	h. Other, (specify):	(1)
	i. Pravastatin sodium (Pravachol):	(1)			
	j. Rosuvastatin (Crestor):	(1)	i. Other, (specify):	(1)
	k. Simvastatin (Zocor):	(1)		`	12
	l. Other, (specify):	(1)	j. Other, (specify):	(1)
	m. None of the above:	(1)	k. None of the above:	(1)
<i>27</i> .	Since the last visit, has the patient taken any antiobesity medications (check all that a. Dexfenfluramine hydrochloride (Redux):	t app (oly): 1)	31. Has the patient taken any strong opiates containing acetaminophen medication in the past 6 months (<i>check all that apply</i>)		
	b. Fenfluramine hydrochloride (Pondimin):	(1)	a. Darvocet:b. Esgic - Plus:	(1)
	c. Methamphetamine hydrochloride (Desoxyn, Gradumet):	(1)	c. Fioricet:	(1) 1)
	d. Orlistat (Xenical):	(1)	d. Lorcet:	(1)
	e. Phendimetrazine tartrate (Adipost,	•	1/	e. Lortab:	(1)
	Bontril):	(1)	f. Norco:	(1)
	f. Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine):	(1)	g. Percocet:h. Talacen:	(1) 1)
	g. Sibutramine hydrochloride monohydrate (Meridia):	(1)	i. Tylenol #3:	(1)
	h. Other, (specify):	(1)	j. Tylenol #4:	(1)
		(17	k. Tylox:	(1)
	i. Other, (specify):		1)	l. Vicodin:	(1)
	in contact, (specify).			m. Wygesic:	(1)
	j. None of the above:	(1)	n. Other, (specify):	(1)
				o. None of the above:	(1)

32.	Since the last visit, has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications (check all that apply):		
	a. Cimetidine (Tagamet):	(1)
	b. Esomeprazole magnesium (Nexium):	(1)
	c. Famotidine (Pepcid):	(1)
	d. Lansoprazole (Prevacid):	(1)
	e. Nizatidine (Axid):	(1)
	f. Omeprazole (Prilosec):	(1)
	g. Ranitidine (Zantac):	(•
	h. Ranitidine bismuth citrate (Tritec):	(1)
	i. Antacids, (specify):	(1)
	j. Other, (specify):	(1)
	k. Other, (specify):	(1)
	l. None of the above:	(1)
33.	Since the last visit, has the patient taken any anticoagulant/antiplatelet medications (check all that apply):		
	a. Clopidogrel (Plavix):	(1)
	b. Dipyridamole:	(1)
	c. Heparin:	(1)
	d. Ticlopide (Ticlid):	(1)
	e. Warfarin (Coumadin):	(1)
	f. Other, (specify):	(1)
	g. Other, (specify):	(1)
	h. None of the above:	(1)

Since the last visit, has the patient taken any systemic corticosteroids (check all that apply):		
a. Betamethasone sodium (Celestone):	(1)
b. Cortisol:	(1)
c. Cortisone:	(1)
d. Dexamethasone (Decadron):	(1)
e. Hydrocortisone (Hydrocortone):	(1/
f. Methylprednisolone (Solu-Medrol):	(1/
g. Prednisolone (Prelone):	(1/
h. Prednisone:	(1/
i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort):	(1/
j. Other, (specify):	(1/
k. Other, (specify):	(1/
l. None of the above:	(1/

Since the last visit, has the patient taken any cardiovascular/antihypertensive medications (check all that apply):			36. Since the last visit, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators		
a. Amiodarone (Pacerone):	(1)	(check all that apply):		
b. Amlodipine besylate (Norvasc):	(1)	a. Conjugated estrogen		
c. Atenolol (Tenormin):	(1)	(Premarin/Prempro):	(1)
d. Benazepril (Lotensin):	(1)	b. Diethylstilbestrol and	(`
e. Captopril (Capoten):	(1)	methyltestosterone (Tylosterone):	(1)
f. Clonidine (Catapres):	(1)	c. Esterified estrogen (Estratab, Menest):	(1)
g. Digoxin (Lanoxin):	(1)	d. Estradiol (Estrace):	(1)
h. Diltiazem (Cardizem):	(1)	e. Ethinyl estradiol (Estinyl):	(1)
i. Doxazosin (Cardura):	(1)	f. Fluoxymesterone (Android-F, Halotestin):	(1)
j. Enalapril (Vasotec):	(1)	g. Levonorgestrel (Norplant):	(1)
k. Felodipine (Plendil):	(1)	h. Medroxyprogesterone (Cycrin,	`	17
l. Furosemide (Lasix):	(1)	Provera):	(1)
m. Hydrochlorothiazide (Esidrix,	,		i. Megestrol (Megace):	(1)
HydroDIURIL):	(1)	j. Methyltestosterone (Android):	(1)
n. Hydrochlorothiazide + triamterene (Dyazide):	(1)	k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin):	(1)
o. Lisinopril (Prinivil, Zestril):	(1)	l. Norethindrone (Micronor):	(1)
p. Losartan potassium (Cozaar):	(1)	m. Norgestrel (Ovrette):	(₁)
q. Losartan potassium with hydrochlorothiazide (Hyzaar):	(1)	 n. Oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, 		1,
r. Metoprolol (Lopressor):	(1)	Levlen, Levlite, Levora, Loestrin,		
s. Nifedipine (Adalat, Procardia):	(1)	Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen,		
t. Perhexiline maleate:	(1)	Ortho-Novum, Ortho Tri-Cyclen,		
u. Propranolol (Inderal):	(1)	Ovral, Tri-Levlen, Triphasil, Trivora, Zovia):	(1)
v. Quinapril (Accupril):	(1)	o. Oxandrolone (Oxandrin):	(1)
w. Terazosin (Hytrin):	(1)	p. Oxymetholone (Anadrol):	(1)
x. Timolol maleate (Blocadren):	(1)	q. Progesterone (Prometrium):	(1)
y. Valsartan (Diovan):	(1)	r. Raloxifene (Evista):	(1)
z. Verapamil (Calan):	(1)	s. Tamoxifen (Nolvadex):	(1)
aa. Other, (specify):	(1)	t. Other, (specify):	(1)
ab. Other, (specify):	(1)	u. Other, (specify):	(1)
ac. None of the above:	(1)	v. None of the above:		1)

37.	Since the last visit, has the patient taken any allergy or asthma medications			41. Since the last visit, has the patient taken any supplements (<i>check all that apply</i>):		
	(check all that apply):			a. Alpha-lipoic acid:	(1)
	a. Albuterol:	(1)	b. Alpha-tocopherol:	(1)
	b. Beclomethasone dipropionate	,		c. Beta-carotene:	(1)
	(Beclovent, Vanceril):	(1)	d. Betaine (Cystadane):	(1)
	c. Budesonide (Pulmicort, Rhinocort):	(1)	e. Calcium (any form):	(
	d. Fluticasone propionate (Flonase, Flovent):	()	f. Carnitine (any form):	(1)
	e. Loratadine (Claritin):	(1)	•	(1)
		(1)	g. Chondroitin (any form):	(1)
	f. Mometasone furoate (Nasonex):	(1)	h. Choline + methionine + betaine + adenosine + pyridoxine (Epocler):	(1)
	g. Triamcinolone acetonide (Azmacort, Nasacort):	(1)	i. Cod liver oil:	(1)
	h. Other, (specify):	(1)	j. Coenzyme Q:	(1)
		Ì	17	k. Dichloroacetate:	(1)
	i. Other, (specify):	(1)	l. Echinacea:	(1)
	20 00000, (0,000,00)	`	1/	m. Fish oil (any form):	(1)
	j. None of the above:	(1)	n. Flax seed oil:	(1)
	j. None of the above.	(1)	o. Garlic:	(1)
38.	Since the last visit, has the patient taken a			p. Ginkgo biloba:	(1)
multivitamin regularly: Yes		1	No	q. Glucosamine (any form):	(1)
	$\binom{100}{1}$		2)	r. Lecithin:	(1)
39.	Since the last visit, has the patient taken			s. Magnesium:	(1)
	vitamins other than multivitamins:	(No (2)		t. Milk thistle:	(1)
	$\binom{1 \text{ es}}{1}$			u. N-acetyl-cysteine:	(1)
	41			v. Potassium (any form):	(1)
40.	Which vitamins has the patient taken			w. S-adenylmethionine (SAM-e):	(1)
	(check all that apply)			x. Saw palmetto:	(1)
	a. Vitamin B (any type):	(1)	y. Selenium:	(1)
	b. Vitamin C:	(1)	z. St. John's Wort:	(1)
	c. Vitamin D:	(1)	aa. Taurine:	(1)
	d. Vitamin E:	(1)	ab. Zinc picolinate:	(1)
	e. Other, (specify):	(1)	ac. Other, (specify):	(
				ac. Oner, (specify).	(1)
				ad Other (specific)	(
				ad. Other, (specify):	(1)

ae. None of the above:

42.	Since the last visit, has patient taken any of the following medications or other supplements/medications (record all other supplements/medications):			H. Summary judgments about specific liver conditions (these judgments are to be made after all of the visit data are collected)
	a. Demeclocycline (Declomycin):	(1)	43. Subscores to compute Child-Pugh Turcotte score
	b. Divalproex (Depakote):	(1)	a. Rate the patient's ascites (check only one):
	c. Doxycycline (Monodox):	(1)	
	d. Isotretinoin (Accutane):	(1)	None (Mild, easily managed (
	e. Levothyroxine (Levoxyl, Synthroid):	(1)	Severe, refractory (
	f. Liothyronine (Cytomel):	(1)	b. Rate the patient's hepatic encephalopathy (<i>check only one</i>):
	g. Methotrexate (Rheumatrex):	(1)	None (
	h. Minocycline (Dynacin, Minocin):	(1)	Mild, easily managed (
	i. Oxytetracycline (Terramycin):	(1)	Severe, refractory (
	j. Penicillamine (Cuprimine, Depen):	(1)	I. Administrative information
	k. Tetracycline (Achromycin):	(1)	44 6 4 50 4 4 50
	l. Trientine hydrochloride (Syprine):	(1)	44. Study Physician PIN:
	m. Ursodeoxycholic acid (Actigall, Urso, Ursodiol):	(1)	45. Study Physician signature:
	n. Valproate sodium (Depacon):	(1)	
	o. Valproic acid (Depakene):	(1)	46. Clinical Coordinator PIN:
	p. Other, (specify):	(1)	47. Clinical Coordinator signature:
	q. Other, (specify):	(1)	
	r. Other, (specify):	(1)	48. Date form reviewed:
	s. Other, (specify):	(1)	day mon year
	t. Other, (specify):	(1)	

u. None of the above:

year

IE - Interim Event Report

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

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

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 21) and the severity code (item 22) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at www.nashcrn.com. Click on Documents and then click on General Documents. Fax the DCC (Attention: Aynur Ünalp-Arida) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).

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

				* *				
A. Center, patient	t, and visit ide	ntificatio	n	C. Patient in	formation			
1. Center ID:	_			9. Date ent	rolled in NAFL not yet enrolled	LD Database (ed.):	enter n if	ра-
2. Patient ID:	_					mon	year	
3. Patient code:				10. Gender:				
4. Date of repor	t:			Male Female			(1) 2)
Ċ	lay n	non	year	11. Age at t	ime of event:		years	
5. Visit code:	_	<u>n</u>		D. Event des	scription		,	
6. Form & revis	ion:	_i_	<u>e</u> 1	12. Date eve	ent started:			
7. Study:	NA	FLD D	atabase 1			mon	year	
B. Visit interval i	dentification				vent associated S study drug us			
8. Most recently or followup)	completed vis	it (screen	ing			Yes (16.	No 2)
a. Date:	lay n	non	year	14. Is the ev study dr	vent due to the jug:	pioglitazone-se	eries	
b. Visit code	: _			Definite	ely yes		(1)
				Probabl	ly yes		(2)
				Possibly	y yes		(3)
				Probabl	y no		(4)
				Definite	ely no		(5)

15.	Is the event due to the vitamin E-series study drug:			20. Describe event:
	Definitely yes	(1)	
	Probably yes	(2)	
	Possibly yes	(3)	
	Probably no	(4)	
	Definitely no	(5)	
16.	Is the event associated with prior TONIC study drug use:			
	Yes (1) 19	(¹	No _2) 	21. Short name for event if applicable (short names for AEs are listed in the CTCAE v3.0 document available at www.nashcrn.com; click on Documents and then click on General Documents):
17.	Is the event due to the metformin-series study drug:			Not applicable $\begin{pmatrix} & & & & & & & \\ & & & & & & \\ & & & & $
	Definitely yes	(1)	
	Probably yes	(2)	
	Possibly yes	(3)	22. Severity grade (severity grades are listed in the
	Probably no	(4)	CTCAE v3.0 document available at
	Definitely no	(5)	www.nashcrn.com; click on Documents and then click on General Documents; use Serious Adverse
18.	Is the event due to the vitamin E-series study drug:			Event Report (AN) to report serious and unex- pected adverse events or call the DCC if unsure what to do:
	Definitely yes	(1)	Not applicable (0)
	Probably yes	(2)	Grade 1 - Mild (1)
	Possibly yes	(3)	Grade 2 - Moderate (2)
	Probably no	(4)	Grade 3 - Severe (3)
	Definitely no	(₅)	Grade 4 - Life threatening or disabling $\begin{pmatrix} 4 \end{pmatrix}$ Grade 5 - Death $\begin{pmatrix} * \\ 5 \end{pmatrix}$
19.	Nature of event (check all that apply)			*Complete and key Death Report (DR) form.
	a. General anesthesia:	(1)	Complete and key Death Report (DR) Joim.
	b. Medication related event:	(, 1)	23. Date event resolved (enter n if event is not yet
	c. Study procedure related event:	(1)	resolved):
	d. Drug interactions:	(1)	day mon year
	e. Worsening of a co-morbid illness:	(1)	24. What action was taken:
	f. Patient reported symptom of hepatotoxicity:	(1)	24. what action was taken:
	g. Hypoglycemia:	(1)	
	h. New-onset diabetes:	(1)	
	i. Pregnancy (patient):	(1)	
	j. Other (specify):	(1)	

		Patient ID:
25. Oth	ner comments on event:	
_		
_		
_		

E. Administrative information

26. Clinical Coordinator PIN:

- **27.** Clinical Coordinator signature:
- **28.** Study Physician PIN: ____ ____
- **29.** Study Physician signature:
- **30.** Date form reviewed:

day	mon	year

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

IR - Liver Imaging Studies Report

Purpose: To record liver imaging study results. **When:** Visits s2, f024, f048, f096, f144, and f192.

Administered by: Clinical Coordinator.

Instructions: Complete this form at each of the visits listed above if the Baseline Medical History (BG) or Followup Medical History (HI) form says that liver imaging study was obtained in the specified period. The form will allow you to skip out of sections that are irrelevant to your patient. What you will report at each visit are the results of the most recent scan of each type done in the year prior to screening (visit s2) or in the period since the prior study visit (after enrollment). These will likely be standard of care scans with results obtained via medical records. In each case, answer the items based on review of the report; the Study Physician must review and approve the findings recorded on this form. Liver imaging studies available at baseline and during followup should be reported on this form even if the patient has definite NAFLD or cryptogenic cirrhosis by histology.

A. Center, patient, and visit identification	10. Findings suggestive of NAFLD, cryptogenic cirrhosis, or others of		
1. Center ID:	significance (check all that apply)		
	a. Fatty infiltration:	(1)
2. Patient ID:	b. Cirrhosis:	(1)
3. Patient code:	c. Hepatomegaly:	(1)
	d. Hepatic mass:	(1)
4. Date of visit:	e. Intrahepatic biliary dilatation:	(1)
day mon 5. Visit code:	f. Extrahepatic biliary dilatation:	(1)
	g. Gallstones/cholelithiasis:	(1)
6. Form & revision: <u>i</u> <u>r</u>	h. Gall bladder polyps:	(1)
7. Study: NAFLD Datab	i. Cholecystectomy:	(1)
7. Study: NAFLD Datas	j. Splenomegaly:	(1)
B. Upper abdominal ultrasound	k. Ascites:	(1)
8. Did the patient have an upper abdominal ultrasound in the past year (<i>screening</i>)/ since the last visit (<i>followup</i>):	l. Other features of portal hypertension (<i>specify</i>):	(1)
(Yes 11	m. Other abnormality (specify):	(1)
9. Date of most recent upper abdominal ultrasound:			
day mon	year n. None of the above:	(1)

C. Upper abdominal CT scan

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

Y	es .	N	lо
(1)	(2)
	1	4.	J

1)

1)

1

12. Date of most recent upper abdominal CT scan:

-		_
day	mon	year

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

f. Hepatic cyst:

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

d. Hepatic mass:	(
e. Hepatic hemangioma:	(

• •	,	
g. Intrahepatic biliary		
dilatation:	(1

h. Extrahepatic biliary dilatation:	(1)
		•

i. Gallstones/cholelithiasis:	(1)
i. Gall bladder polyps:	((ر

k. Cholecystectomy:	(1
l. Splenomegaly:	(1

m. Ascites:	(1/
n. Other features of portal		

hypertension (specify):

Other abnormality (specify):	(1

p. None of the above:	(1.

D. Upper abdominal MRI

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



15. Date of most recent upper abdominal MRI:

-		_
day	mon	year

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

a. Fatty infiltration:	(1)
b. Cirrhosis:	(1)
c. Hepatomegaly:	(1)

d. Hepatic mass:	(1)
e. Henatic hemangioma:	(.)

f. Hepatic cyst:	(1)
σ Intrahenatic hiliary		

g. Intrahepatic biliary dilatation:	(1)
h Extrahenatic hiliary		

dilatation:	(1
i. Splenomegaly:	(1)
i. Ascites:	(

k. Other features of portal		
hypertension (specify):	(1)

l.	Other abnormality (specify):	(1)

m. None of the above:	(,)	

Patient ID:	 	

E. Administrativ	e information
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17.	Study Physician PIN:		
18.	Study Physician signature:		
19.	Clinical Coordinator PIN:		
20.	Clinical Coordinator signature:		
21.	Date form reviewed:	-	
	day 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 s1. If more than one LD form is needed, use visit code "n" on the second LD form.

Administered by: Clinical Coordinator.

Respondent: Patient, 18 years of age or older, without help from spouse or family.

Instructions: In addition to actual consumption levels (quantity), attention is focused upon the frequency of use, variability in consumption, types of beverages, life events that mark a change in drinking pattern, solitary versus social drinking, and time of day when alcohol is consumed. Flash Card #15, Drink Equivalents, may be used with this interview.

The interviewer begins by recording the patient's alcohol consumption behavior during the first year that he/she drank on a regular basis (at least one drink per month). Then, the patient is asked to think of when his/her drinking behavior changed in any appreciable way. In a chronological fashion, the interviewer traces the patient's alcohol consumption behavior from the age of first regular drinking to the present. Flash Card #16, Patterns of Alcohol Intake, provides sample language for the interviewer. Each LD form allows for describing six drinking phases. Use a second LD form (visit code "n") if needed to describe additional drinking phases. If this is the second LD form, skip sections B and C and start with item 20.

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

A. Center, patient, and visit identification

1.	Center ID:				
2.	Patient ID:				
3.	Patient code:				-
4.	Date of visit (date po	atient co	mpleted	the for	m):
	a	mon	·	y	ear
5.	Visit code:				
6.	Form & revision:		_1	<u>d</u> _	_1_
7.	Study:	N/	AFLD I	Databa	ase 1

B. Lifetime alcohol consumption

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



Patient ID:		

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:

yrs

Months:

mos

How old were you at the end of first stage:

Years:

yrs

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

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

drinks

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

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

Beer

Liquor

Wine

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)

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

Frequent (15 days or more per month)

No Yes

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):

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

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	 0/6	

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:

a.	Years:	yrs
b.	Months:	mos

23. During this phase, how many drinks would you have on average per occasion (*drinking day*):

# drinks	

24. How many days per month would you generally drink at this level (*write* "*m*" *if not drinking*):

# days	

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

#	drinks	

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

26. What type of beverage would you usually consume in an average month (record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000"):

Beer	 %	
Liquor	 %	
Wine	 %	

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

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

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



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):

-33		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)
1	Emotional ((.)	(.)

Patient ID:		

30. What percentage of time would you drink alone, and what percentage of the time with at least one other person (record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):

Alone %
With others

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

Morning %

Afternoon %

Evening %

E. Next subsequent phase

32. Read as written: "We have just discussed your drinking habits when you first began to drink regularly and at a subsequent phase. Now I want you to think to when your drinking behavior was different in a significant way from the previous phase. This could be the next 6 months or perhaps 2 or 5 years later. Can you think of any events in your life that changed and may have altered your drinking habits": Yes No

Yes No () () 2) **81.**

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: ______

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 `	ľ	Vо
(1)	(2)
	42] ←	

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

		Posit	ive	Nega	ative	Net	ıtral
a.	Marital/family	. (1)	(2)	(3)
b.	Work	. (1)	(2)	(3)
c.	School	. (1)	(2)	(3)
d.	Medical	. (1)	(2)	(3)
e.	Residence	. (1)	(2)	(3)
f.	Legal/jail	. (1)	(2)	(3)
g.	Financial	. (1)	(2)	(3)
h.	Peer group	. (1)	(2)	(3)
i.	Drug abuse	. (1)	(2)	(3)
j.	Treatment	. (1)	(2)	(3)
k.	Death	. (1)	(2)	(3)
l.	Emotional	. (1)	(2)	(3)

42. What percentage of time would you drink alone, and what percentage of the time with at least one other person (record the relative percentages of "Alone" and "With others"; this section should add up to 100%; if not drinking, percentages should be "000"):

Alone	%	
With others		

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

Morning				
C		%		
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":



mos

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:

Voore

а.	rears.	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):

	Positi	ive	Nega	ative	Net	ıtral
Marital/family	. (1)	(2)	(3)
Work	. (1)	(2)	(3)
School	. (1)	(2)	(3)
Medical	. (1)	(2)	(3)
Residence	. (1)	(2)	(3)
Legal/jail	. (1)	(2)	(3)
Financial	. (1)	(2)	(3)
Peer group	. (1)	(2)	(3)
Drug abuse	. (1)	(2)	(3)
Treatment	. (1)	(2)	(3)
Death	. (1)	(2)	(3)
Emotional	. (1)	(2)	(3)
	Work	Marital/family (Work (School (Medical (Residence (Legal/jail (Financial (Peer group (Drug abuse (Treatment (Death (Work (1) School (1) Medical (1) Residence (1) Legal/jail (1) Financial (1) Peer group (1) Drug abuse (1) Treatment (1) Death (1)	Marital/family . (Marital/family . (1) (2) Work (1) (2) School (1) (2) Medical (1) (2) Residence (1) (2) Legal/jail (1) (2) Financial (1) (2) Peer group . (1) (2) Drug abuse . (1) (2) Treatment . (1) (2) Death (1) (2)	Marital/family . (

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

66. 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:	<u> </u>
		yrs
b.	Months:	

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

a.	Years:	
		yrs
b.	Months:	
		mos

Patient ID:		

59.	During this phase, how many drinks would you have on average per occasion (<i>drinking day</i>):	65.	What was your po you say that it had (undesirable), or a (for each event th
	# drinks	-	drinking pattern,
60.	How many days per month would you generally drink at this level (write "m" if not drinking):		"2" for negative effect):
61.	# days What is the most or maximum number of drinks you would have in any one day:	-	a. Marital/famb. Workc. Schoold. Medicale. Residence
	# drinks	-	f. Legal/jail .g. Financial .
	(Note: This is the maximum number that the patient actually would drink, not an estimate of his/her potential capacity.)		 g. Financial . h. Peer group i. Drug abuse j. Treatment k. Death l. Emotional
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"):	66.	What percentage and what percents other person (reconstruction) and "Wadd up to 100%;
	Beer	-	should be "000", Alone
	Liquor	-	
	Wine		With others
63.	How would you rate your usual style of drinking during an average month (check the appropriate category);	67.	During what time your drinking? C of time during the (record the relati afternoon and eve
	Abstinent (1) Occasional (less than 15 days) (2)		to 100%; if not di be "000"):
	Weekend mainly Binge (at least 3 days heavy drinking) Frequent (15 days or more per month) (3) (4)))	Morning
64.	Did any important event or events occur during		Afternoon

this period that altered your usual drinking habits:

Yes

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

		Positi	ve	Nega	itive	Neu	ıtral
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	 0/2	

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 No () 2

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

Years:

yrs

b. Months:

mos

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

a. Years:

yrs

b. Months:

mos

71. During this phase, how many drinks would you have on average per occasion (*drinking day*):

drinks

72. How many days per month would you generally drink at this level (*write "m" if not drinking*):

days

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

drinks

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

74. What type of beverage would you usually consume in an average month (record the relative percentages of beer, liquor or wine; this section should add up to 100%; if not drinking, percentages should all be "000"):

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):

	Posi	itive	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 (1)	Ì	2)	Ì	2)

78.	What percentage of time w and what percentage of the other person (record the re "Alone" and "With others add up to 100%; if not driv should all be "000"):	time with lative per "; this see	n at least one reentages of ction should
	Alone		%
	With others		%
79.	During what time of the dayour drinking? Could you of time during the evening, (record the relative percenafternoon and evening; this to 100%; if not drinking, pube "000"):	give me t afternoon tages of s section	he percentage n and morning morning, should add up
	Morning		%
	Afternoon		%
	Evening		<u></u> %
I. Nu	mber of phases		
80.	Are there any additional su		phases: Yes No * 1) (2)
	* If yes, complete a second Skip sections B and C on se		
J. Adr	ninistrative information		
81.	Clinical Coordinator PIN:		
82.	Clinical Coordinator signat	ure:	

83. Date form reviewed:

mon

year

A

LP - Symptoms of Liver Disease (Children)

Purpose: To obtain the patient's view of his/her liver disease symptoms.

When: Visits s1, f048, f096, f144, and f192.

Administered by: Self-administered (age 13-17), interviewer administered (age 2-12). Clinical Coordinator must be available to answer questions and review for completeness.

Respondent: Patient, age 2 through 17. Patient age 13 or older should complete the form without help from family. Clinical Coordinator/parent should assist patient age 2-12.

Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-4. If the form is self-administered by the patient, the patient should meet with the Clinical Coordinator, be trained in the completion of the form, and then should complete pages 2-4. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should then complete section B below.

Ce	nter, patient, and vis	sit identification	n		Administrative information		
1.	Center ID:				(To be completed by Clinical Coordinator after survey is completed.)		
2.	Patient ID:			8.	3. How was the questionnaire completed:		
3.	Patient code:				Self-administered by patient/parent	(1)
4.	Date of visit:				10.	↓	
		mon	year		Interview in English Interview with translator	(2	
5.	Visit code:			9.	O. Who was the respondent (check all that app	<i>by</i>):	
6.	Form & revision:	l NAELD	p 1		a. Patient:b. Patient's mother or female guardian:	(₁	
7.	Study:	NAILD	Database <u>1</u>		c. Patient's father or male guardian:d. Other (specify):	(1)
					specify		-
				10.	a. PIN: b. Signature:		_
				11.	Date form reviewed:		•
					day mon ye	ar	_

Affix le	abel here
Patient ID:	
Patient code:	
Visit code:	

Symptoms of Liver Disease

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

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

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

Circle one for each symptom

Degree of bother

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

Affix l	abel here
Patient ID:	
Patient code:	
Visit code:	

Circle one for each symptom

Degree of bother

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

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

Circle one

		Circle on
	I feel normal and am not tired (If this is how you feel, please circle "1" and s	20
	to item number 17 – Thank you!)	-
	• •	
	I feel tired some of the time, but can do what I want to do without trouble	
	I feel tired, and do what I want but with trouble	
	I feel tired and it keeps me from doing what I want to do	4
14.	How often are you bothered by being tired (choose only one):	
	All day, every day	1
	Part of the day, every day	
	At least part of several days a week	
	At least part of one day a week	
	Not as much as above	5
15.	Are you tired (choose only one):	
	When you wake up in the morning	1
	Or does it come on with the day	
	Or does it have no time pattern	3
16.	Do you feel more tired the day after you exercise or have a lot of activity:	
	Yes	1
		_

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

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

Very good
Good
Fair
Poor
Awful

18. Today's date:

Thank you for completing this questionnaire.

LQ - Symptoms of Liver Disease

Purpose: To obtain the patient's view of his/her liver disease symptoms.

When: Visits s1, f048, f096, f144, and f192.

Administered by: Self-administered during the visit, but Clinical Coordinator must be available to answer questions and review for completeness.

Respondent: Patient, 18 years of age or older.

Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-4. The patient should complete pages 2-4 during the visit. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should then complete section B below.

A. Ce	enter, patient, and vi	sit identification	B. Administrative information (To be completed by Clinical Coordinator after				
1.	Center ID:		survey is completed.)				
2.	Patient ID:		8. Clinical Coordinator a. PIN:				
3.	Patient code:		b. Signature:				
4.	Date of visit:						
	day	mon year	9. Date form reviewed:				
5.	Visit code:		day mon year				
6.	Form & revision:	<u>l q 1</u>	_				
7.	Study:	NAFLD Database	1				

1 of 4

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

Symptoms of Liver Disease

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

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

10. During the last month, how much have you been bothered by the following: *Circle one for each symptom*

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

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

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

		Circle one
	I feel completely normal and have no fatigue (circle "1" and go to	1
	item # 16)	
	I have some fatigue, but I can do what I want to do without difficulty	2
	I have fatigue, and I do what I want to do but with difficulty	3
	I have fatigue and it keeps me from doing what I want to do	4
	I have fatigue that prevents me from working	5
	I have fatigue that prevents me from working and requires that	
	I have assistance to carry out normal activities of living	
	I am worse off than any of these statements suggest	7
12.	How frequently are you bothered by fatigue (choose only one):	
	All day, every day	1
	Part of the day, every day	2
	At least part of several days a week	
	At least part of one day a week	4
	Less frequently	5
13.	Is your fatigue typically present (choose only one):	
	When you wake up in the morning	1
	Or does it come on with the day	2
	Or does it have no time pattern	
14.	Is your fatigue typically worse the day after a period of extra activity or e	xercise:
	Yes	1
	No	2

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

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

	Cir	cle one
	Yes	1
	No	2
16.	In general, how have you felt overall in the past month:	
	Very good	. 1
	Good	
	Fair	
	Poor	. 4
	Awful	. 5
17.	Today's date:	

Thank you for completing this questionnaire.

LR - Laboratory Results - Tests Done During Screening and Followup

Purpose: To record archival and current laboratory test results for tests done during both screening and followup. **When**: Visits s2, f048, f096, f144, and f192.

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

Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Please note that the units 10^3 cells/ μ L, 1000 cells/ μ L, and 10^9 cells/L are equivalent. Call the DCC if you have questions about conversion or how to record a value. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

A. Center, patient, and visit identification	C. Chemistries and HbA1c				
1. Center ID:	13. Date of blood draw for chemistries:				
2. Patient ID:	day mon year Date must be within the required time window: within 6 months of screening or in the time window				
3. Patient code:	for the followup visit (check the patient's Database visit time window guide).				
4. Date of visit (date form was initiated):	14. Sodium:* mEq/L				
day mon year	15. Potassium:* •				
5. Visit code:	mEq/L				
6. Form & revision:	16. Chloride:*				
7. Study: NAFLD Database 1	17. Bicarbonate:*				
B. Hematology	18. Calcium:*				
8. Date of blood draw for complete blood count:	mg/dL 19. Phosphate:*				
day mon year Date must be within the required time window: within 6 months of screening or in the time window	20. Blood urea nitrogen (BUN):mg/dL				
for the followup visit (check the patient's Database visit time window guide).	21. Creatinine:				
9. Hemoglobin:	22. Uric acid:				
10. Hematocrit:	* Optional: If not done, enter "m".				
11. White blood cell count (WBC):	23. Date of blood draw for HbA1c:				
$\frac{\bullet}{10^{3} \text{ cells/}\mu\text{L or } 10^{9} \text{ cells/}\text{L}}$	day mon year Date must be within the required time window: within 3 months of screening or in the time window				
12. Platelet count:	for the followup visit (check the patient's Database visit time window guide).				

cells/ µL

			Patient ID:	
24. HbA1c:	<u> </u>	36. Date of blood draw for alph	alpha feto protein:	
D. Liver panel and alpha feto p	rotein	Date must be within the i	mon year required time window:	
25. Date of blood draw for liver	panel: 	within 6 months of screenin for the followup visit (check visit time window guide). done.	the patient's Database Record "m" if test not	
day m Date must be within the re within 6 months of screening for the followup visit (check the visit time window guide).	or in the time window	37. Alpha feto protein:	•	
visit time window guide).		n	ng/mL	
26. Bilirubin (total):		E. Fasting lipid profile		
27. Bilirubin (direct):	mg/dL	Fasting is defined as not water for greater than or e to blood draw.	thing by mouth except equal to 12 hours prior	
28. Aspartate aminotransferase (mg/dL AST)	38. Date of blood draw for fast profile:	ing lipid	
		·	mon year	
a. Upper limit of normal:	U/L U/L	Date must be within the r within 6 months of screening for the followup visit (check	required time window: g or in the time window	
b. Lower limit of normal:		visit time window guide).	inepatient s Batabase	
	U/L	a. Triglycerides:		
29. Alanine aminotransferase (A	LT)		mg/uL	
_		b. Total cholesterol:		
a. Upper limit of normal:		c. HDL cholesterol:		
b. Lower limit of normal:			mg/dL	
	U/L	d. LDL cholesterol:	mg/dL	
30. Alkaline phosphatase			mg/uL	
a. Upper limit of normal:	U/L	F. Fasting glucose and insulin	d: 1 d	
	U/L	Fasting is defined as not water for greater than or e	thing by mouth except equal to 12 hours prior	
b. Lower limit of normal:		to blood draw.		
31. Gamma glutamyl transferase	(GGT):	39. Date of blood draw for fast and insulin levels:	ing glucose	
			mon year	
32. Total protein:	g/dL	Date must be within the n within 6 months of screening for the followup visit (check visit time window guide).	g or in the time window	
33. Albumin:	<u>•</u>	a. Serum glucose:		
	2	b. Serum insulin:	•	
34. Prothrombin time (PT):	sec		μU/mL	

35. International normalized ratio (INR):

Patient ID:		

			_	_		_
(;	A c	lmin	nictra	ative	infor	mation

40. Study Physician PIN:

41. Study Physician signature:

42. Clinical Coordinator PIN: ____ ____

43. Clinical Coordinator signature:

44. Date form reviewed:

day mon year

LS - Laboratory Results -Tests Done only During Screening

Purpose:	To record	archival and	l current	results of	laboratory	tests do	ne only	at screenin	g.

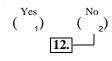
When: Visit s1.

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

Instructions: Laboratory test results may be obtained from chart review. The acceptable time interval for archival laboratory data is specified for each test and recorded next to the date of blood draw. Laboratory tests should be repeated if the blood draw date is outside the specified time interval. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have questions about conversion or how to record a value. If is checked for any item, you do not need to complete the rest of the form and the form may not be keyed.

A. Center, patient, and visit identification	c. Hepatitis B surface antibody (anti-HBs)*:
1. Center ID:	Positive (,)
	Negative (2)
2. Patient ID:	d. Hepatitis C antibody (anti-HCV) (indicate result as negative if EIA is
3. Patient code:	positive but RIBA is negative or if RIBA is indeterminate but HCV RNA is negative):
4. Date of visit:	Positive (1)
	Negative (2)
day mon year	e. Hepatitis C virus RNA:
5. Visit code: _s1	Positive ()
6. Form & revision:	Negative (2)
	Not available (2)
7. Study: NAFLD Database 1	f. Hepatitis A virus antibody (anti-HAV, total):
B. Screening etiologic tests	Positive (1)
	Negative (2)
8. Date of blood draw for serological assays	Not available (3)
to exclude viral causes of chronic liver disease:	·
disease.	C. Iron
day mon year Repeat if date is greater than 5 years prior to screening.	9. Date of blood draw for iron overload screening:
If the patient is judged by Study Physician to have a high-risk lifestyle, repeat if date is greater than 6 months prior to screening. *Record as "m" if test is not done.	day mon year Repeat if date is greater than 5 years prior to screening.
a. Hepatitis B surface antigen (HBsAg):	a. Iron: μg/dL
Positive (₁)	MP CE
(E)rg) — '	b. Total iron binding capacity:
Negative (2)	μg/dL
, 2	c. Ferritin:
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. Is hepatic iron index available:

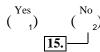


11. Hepatic iron index:

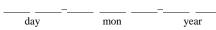
•	
μMo1/g/year	

D. HFE gene analysis

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



13. Date of blood draw for HFE gene analysis:

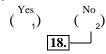


14. Type of abnormality (*WT* = *wild type*; *check only one*):

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

E. Ceruloplasmin

15. Is patient 40 years old or younger:

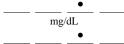


16. Date of blood draw for ceruloplasmin: (required only if patient is 40 years old or younger):



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

17. Ceruloplasmin



a. Upper limit of normal:

	mg/dL
b. Lower limit of normal:	•
	mg/dL

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

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

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

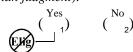
 - **b.** Lower limit of normal: _____ mg/dL
- **20.** A1AT phenotype (*if unknown record as "m"*)
 - **a.** Pi Z heterozygote:

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

b. Pi ZZ homozygote:



21. A1AT deficiency (physician judgment):



G. Autoantibody studies

22. Date of blood draw for autoantibody tests:

day mon year

peat if date is greater than 5 years prior to

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

23. Antinuclear antibody (ANA):

Positive (*₁)
Negative (_₂)

*If results are given as units, record as "n," and key the actual result in the General Comments. 24. Antismooth muscle antibody (ASMA):

Positive (*1)
Negative (25.

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

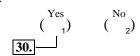
25. Antimitochondrial antibody (AMA)*:

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

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

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

26. Is the patient 18 or older:



27. Lymphocytotoxic antibody (LCA)*:

Positive (1)
Negative (28.

- **a.** If positive, LCA: 1/____ ____
- **28.** Antibody to liver-kidney microsomal antigen (LKM1)*:

Positive (1)
Negative (2)

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

29. Rheumatoid factor (RF)*:

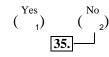
Positive (1)
Negative (2)

a. If positive, RF: ____ ___ ___

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

H. Immunoglobulin levels

30. Are immunoglobulin levels available:



31. Date of blood draw for immunoglobulin levels:

day mon year

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

I. Other screening blood tests

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

Repeat if date is greater than 5 years prior to screening. *Optional if patient under age 18, enter "m" if not done.

36. Thyroid stimulating hormone:

Patient ID:	 	

J. Administrative information

37. Study Physician PIN:

38. Study Physician signature:

39. Clinical Coordinator PIN:

40. Clinical Coordinator signature:

41. Date form reviewed:

42. Date form reviewed:

43. Date form reviewed:

MA - Modifiable Activity Questionnaire

Purpose: To obtain the patient's physical activity.

When: Visits s2, f048, f096, f144, and f192.

Administered by: Interview administered or self-administered, depending on the age of the patient. Parents may assist with completion, if needed. Clinical Coordinator must be available at visits to answer questions and to review completed forms.

Respondent: Patient, age 8-17.

Instructions: The Clinical Coordinator should complete Part A below and attach a label to each of pages 2-3. The patient should meet with the interviewer, be trained in completion of the form, and then should complete pages 2-3. If needed, the Clinical Coordinator may administer the interview to the patient. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B below.

4.	Center, patient, and	l visit identification	B. Administrative information
1.	Center ID:		(To be completed by the Clinical Coordinator after survey is completed).
2.	Patient ID:		8. How was the questionnaire completed: Self-administered by patient/parent (1)
3.	Patient code:		10.
4.	Date of visit (date pa	atient completed the form):	Interview in English (2) Interview with translator (3)
		month year	9. Who was the respondent (check all that apply) a. Patient: b. Patient's mother or female guardian: (1)
5.	Visit code:		c. Patient's father or male guardian: (1) d. Other, specify: (1)
6.	Form & revision:	<u>m a 1</u>	
			10. Clinical Coordinator
7.	Study:	NAFLD Database 1	a. PIN:
			b. Signature:
			11. Date form reviewed:
			day month year

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

Modifiable Activity Questionnaire

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

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

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

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

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

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

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

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

	Circle one
None	
1 activity	2
2 activities	
3 activities	
4 or more activities	5
What activities did you compete in?	

,______

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

PAST YEAR LEISURE-TIME PHYSICAL ACTIVITY

1						. Do not include time spent in school ated in during the last year.
() 0 () 0 () 1 () 1 () 1 () 2	 Aerobics Basketball Cheerleading Garden/Yard Work Ice Skating Skateboarding Softball Tennis Weight Training (Competitive))))))))	05. 08. 11. 14. 17. 20. 23.	Band/Drill Team Bicycling Dance Class Gymnastics Roller Skating Snow Skiing Street Hockey Volleyball Wrestling)))))))	03. Baseball 06. Bowling 09. Football 12. Hiking 15. Running and Exercise 18. Soccer 21. Swimming 24. Water Skiing 27. Others:

Check the months you did each activity and then estimate the amount of time spent in each activity.

Activity Code #	Activity	J A N	F E B	M A R	A P R	M A Y	J U N	J U L	A U G	S E P	O C T	N O V	D E C	Months per Year	Days per Week	Minutes per Day

17. Today's date:

MV - Missed or Incomplete Visit

Purpose: Record reason(s) for missed or incomplete visit.

When: At the close of a visit window for any missed followup visit or for any followup visit with specific forms not completed. Use visit code f024, f048, f096, f144, or f192.

Respondent: None.

Completed by: Clinical Coordinator.

Instructions: Complete this form when a patient fails to complete a visit or specific visit procedures (resulting in

missing forms) within the time window for the visit.

A. (Center,	patient,	and	visit	identificat	ion
-------------	---------	----------	-----	-------	-------------	-----

- **1.** Center ID: ____ ___ ___
- **2.** Patient ID: ____ ___ ____
- **3.** Patient code: ____ ___
- **4.** Date of visit:

-		_
day	mon	year

- **5.** Visit code: __f_ ___ ___
- 7. Study: NAFLD Database 1

B. Reason for completion of this form

8. Was the entire visit missed:

C. Missed visit information

- **9.** Reason for missed visit (check all that apply)
 - **a.** Patient was ill:
 - **b.** Patient was temporarily away from area:
 - **c.** Patient refused to return:
 - **d.** Patient has permanently moved from the area:
 - e. Unable to contact patient:
 - **f.** Other (specify):

specify

- **a.** Telephoned patient: (1)
- **b.** Mailed reminder card: (
- **c.** Other (specify):

14. —

D. Missed form information

11. Check form(s) not completed (check required forms that were missed)		
a. Food Questionnaire Documentation (BD):	(1)
b. Blood Processing for Plasma and Serum (BP):	(1)
c. Followup Medical History (HI):	(1)
d. Liver Imaging Studies Report (IR):	(1)
e. Symptoms of Liver Disease (Children) (LP):	(1)
f. Symptoms of Liver Disease (LQ):	(1)
g. Laboratory Results - Tests Done During Screening and Followup (LR):	(1)
h. Modifiable Activity Questionnaire (MA):	(1)
i. Physical Activity (PA):	(1)
j. Physical Examination (PE):	(1)
k. Focused Physical Examination (PF):	(1)
1. Pediatric Quality of Life: Parent of adolescent age 13-17 (PQ):	(1)
m. Pediatric Quality of Life: Parent of child age 8-12 (PR):	(1)
n. Pediatric Quality of Life: Parent of child age 5-7 (PS):	(1)
o. Pediatric Quality of Life: Parent of toddler (PT):	(1)
p. Pediatric Quality of Life: Child age 5-7 (PV):	(1)
q. Pediatric Quality of Life: Child age 8-12 (PW):	(1)
r. Pediatric Quality of Life: Adolescent age 13-17 (PY):	(1)
s. MOS 36-Item Short-form Health Survey (QF):	(, 1)
t. Other (specify):	(1)
specify		

12. Reason form(s) not completed (check all that apply) a. Patient was ill: **b.** Patient refused procedure: **c.** Parent refused procedure: **d.** Procedure forgotten: **e.** Other (specify): specify **13.** Attempts made to complete form(s) *(check all that* apply) **a.** Attempted to reschedule procedure: **b.** Attempted to collect interview data by phone from patient/family: **c.** Attempted to gain patient/parent cooperation: **d.** Other (specify): specify E. Administrative information 14. Clinical Coordinator PIN: **15.** Clinical Coordinator signature: **16.** Date form reviewed: day mon year

Purpose: To obtain the patient's physical activity.

When: Visits s2, f048, f096, f144, and f192.

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

Respondent: Patient, 18 years of age or older, without help from spouse or family.

Instructions: The Clinical Coordinator should complete section A below and attach a label to each of pages 2-4. **Screening:** The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-4. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B below. **Followup:** Pages 2-4 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B. Item 4 should be completed with the date the patient wrote in item 39. If the patient did not write in a date, use the date of the study visit for the visit date.

A. Ce	enter, patient, and vi	sit identification	1			itive informa apleted by Clia		inator after
1.	Center ID:			,		ompleted.)	nicai Coorai	indior djier
2.	Patient ID:			8.	Clinica a. P	l Coordinator		
3.	Patient code:					ignature:		
4.	Date of visit (date p	atient completed	the form):					
	day	mon	year	9.	Date fo	rm reviewed:		
5.	Visit code:				da		mon	year
6.	Form & revision:	<u> </u>	<u>a</u> 1					
7.	Study.	NAFLD	Database 1					

Affix label her	·e
Patient ID:	
Patient code:	i
Visit code:	

PA - Physical Activity

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

C. Non-Recreational Activity (Work Related)

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

10.	Circle one Level of activity that best describes your usual non-recreational activity.
	Vigorous or strenuous activity: (involves heavy lifting, digging, handling heavy tools or equipment, or any other activity causing you to work up a sweat or get out of breath)
	Moderate activity:
	Light activity:
11.	On average, how many hours per day do you spend at this level of activity?
	Hours
12.	On average, how many hours per day do you spend sitting down?
	Hours

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

D. Recreational Activity (Non-Work Related)

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

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

Affix label here		
Patient ID:	_ ¦	
Patient code:	_	
Visit code:	_	

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

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

PE - Physical Examination

Purpose: Record detailed physical exam findings. **When**: Visits s1, f048, f096, f144, and f192.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Details of the protocol for height, weight, waist and hip measurements are found in NAFLD Database SOP, Part I. In brief: Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other. Skin fold and mid-upper arm circumference should be measured on the right arm with the elbow extended and the arm relaxed. Repeat skin fold measurements until you have two measurements within 10 mm of each other. Repeat mid-upper arm circumference measurements until you have two within 1.5 in (3.8 cm) of each other.

A. Center, patient, and visit iden	tification	9. Weight (shoes off)	
1. Center ID:		a. Weight, 1st measurement:	_
2. Patient ID:		b. Weight, 2nd measurement:	•
3. Patient code:		c. Units:	<u> </u>
4. Visit date:		Pounds Kilograms	$\begin{pmatrix} & & & \\ & & 1 \end{pmatrix}$
day mo	n year	10. Waist (standing, at midpoint betwoof iliac crest and lowest part of repeat waist measurements untimeasurements within 4 in (10.2 c	of costal margin; til you have two
6. Form & revision:	<u>p</u> <u>e</u> <u>2</u>	a. Circumference, 1st measurement	ent:
7. Study: NAFI	LD Database 1	waist c b. Circumference, 2nd measuren	ircumference
B. Measurements		waist c	ircumference
8. Height (shoes off)		c. Units:	incumerence (
a. 1st measurement:	•	Inches Centimeters	$\begin{pmatrix} & & & & & & & & \\ & & & & & & & \\ & & & & & & & \\ & & & & & & & \\ & & & & & & & \\ & & & & & & \\ & & & & & & \\ & & & & & & \\ & & & & & \\ & & & & & \\ & & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & \\ & & & \\ & & & \\ \end{pmatrix}$
b. 2nd measurement:	<u> </u>	11. Hip (standing, at fullest part of th measurements until you have tw within 4 in (10.2 cm) of each oth	vo measurements
c. Units: Inches	(1)	a. Circumference, 1st measurement	ent:
Centimeters	$\begin{pmatrix} & 1 \\ & 2 \end{pmatrix}$		<u> </u>
		1	cumference
		b. Circumference, 2nd measuren	nent:
		hin cir	cumference
		c. Units:	Camillelellee
		Inches	(,)
		Centimeters	$\begin{pmatrix} & & & & & \\ & & & & & \\ & & & & & \end{pmatrix}$

12. Triceps (right arm, with		18. Acanthosis nigricans (check only one):		
have two within 10 mi	d measurements until you m of each other; repeat	Absent (not detectable on close inspect	ion) (0
mid-upper arm circumference measurements until you have two within 1.5 in (3.8 cm) of each other)		Present (clearly present on close		
a. Skin fold, 1st measure	ement:	inspection, not visible to casual observe extent not measurable)	er, (1)
		Mild (limited to base of skull, not		
b. Skin fold, 2nd measur		extending to lateral margins of neck, < 3 inches in breadth)	(2)
, 	<u> </u>	Moderate (extending to lateral margins	,	2/
	mm	of neck, 3-6 inches in breadth, not visib		\
c. Mid-upper arm circum measurement:	nference, 1st	from patient's front)	(3)
measurement.	• • • • • • • • • • • • • • • • • • •	Severe (extending anteriorly, > 6 inche	s in	`
d. Mid-upper arm circur	arm circumference	breadth, visible from front)	(4)
measurement:	•	19. Other skin abnormality (check all that a	(pply	
	arm circumference	a. Jaundice:	(1)
e. Units for arm circumf	erence:	b. Palmar erythema:	(•
Inches	(1)		(1)
Centimeters	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	c. Spider angiomata:	(1)
13. Temperature		d. Other (specify):	(1)
(Oral or other, as appro	opriate for age)			
a. Degrees:	<u> </u>	e. None of the above:	(1)
, and the second		20. Head, eyes, ears, nose, throat:		
b. Scale:		Normal	()
Fahrenheit	(₁)	Tomai	22 _	1/
Centigrade	(₂)	Abnormal		2)
14. Blood pressure				_
-		21. Abnormality of the head, eyes, nose, throat		
a. Systolic:		(check all that apply)		
	mmrg	a. Jaundice:	(1)
b. Diastolic:	mmHg	b. Other (specify):	(1)
15. Resting radial pulse:		specify		
	beats/minute	эрсепу		
16. Respiratory rate:		22. Neck:		
	breaths/minute	Normal	(1)
C. Examination findings			23. —	
_		Abnormal	(2)
17. Skin:		specify abnormality		
Normal	(₁)	specify abilormanty		
Abnormal	20. (₂)			

23.	Τ.		m	ha	tia
4.).	L	vii	ш	па	LIC.

Normal		(1)
Abnormal		24.) ₂)
-	specify abnormality		

24. Chest and lungs:

Normal	(1)
Abnormal	(2
spec	rify

25. Heart:

Normal		(1)
Abnormal		26.	2)
	specify abnormality		_

26. Abdomen:

Normal	(1)
	28.
Abnormal	(

- **27.** Abdomen abnormality *(check all that apply)*
 - a. Ascites: (
 b. Obese: (
 c. Other (specify): (

 specify
- **28.** Liver and spleen:

Normal	(1)
Abnormal	30. (₂)

- **29.** Abnormality of liver or spleen (check all that apply)
 - **a.** Hepatomegaly: (if checked, span from right midclavicular line):

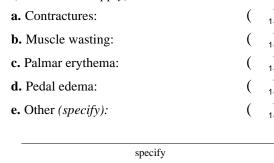
			
	cm		
b. Splenomegaly:		(1
c. Other (specify):		(1

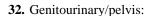
specify

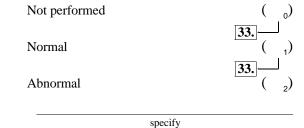
30. Extremities:

Not performed	$\begin{pmatrix} 0 \end{pmatrix}$
Normal	32. (₁)
Abnormal	32.

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







33. Nervous system:

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

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

a. Mental status abnormal:	(1)
b. Asterixis:	(1)
c. Other (specify):	(1)
specify		

Female Tanner Staging

- 40. Breast stage: 1-5
- **41.** Pubic hair stage: 1-5
- **42.** Has menarche occurred:

menarche:

(Y	res 1)	(No	,
		44.	

age in years

35. Is Tanner staging required for this participant (Note: Required at screening visit if participant is 17 years old or

younger.) (check only one):

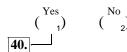
Yes, participant has not reached full sexual maturity or is 17 years old or younger: No, participant is 18 years old or older

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



36. Is the patient female:

D. Tanner Staging





Male Tanner Staging

37. Genital stage:

1-5

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



39. Pubic hair stage:





E. Administrative information

43. What was the participant's age at

- 44. Study Physician PIN:
- **45.** Study Physician signature:
- 46. Clinical Coordinator PIN:
- **47.** Clinical Coordinator signature:

48. Date form reviewed:

_		_
day	mon	year

PF - Focused Physical Examination

Purpose: Record focused physical exam findings.

When: Visit f024.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Details of the protocol for height, weight, waist and hip measurement are found in the NAFLD Database SOP Part I. In brief: height, weight, waist and hips should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other.

A. Center, patient, and vis	sit identification	9. Weight (shoes off)	
1. Center ID:		a. 1st measurement:	_
2. Patient ID:		b. 2nd measurement:	<u> </u>
3. Patient code:		c. Units:	<u> </u>
		Pounds	(1)
4. Visit date:		Kilograms	(₂)
day 5. Visit code:	mon year	10. Waist (standing, at midpoint before of iliac crest and lowest point repeat waist measurements u measurements within 4 in (10.2)	t of costal margin; ntil you have two
6. Form & revision:	_pf2_	a. 1st measurement:	
7. Study:	NAFLD Database 1	b. 2nd measurement:	
B. Measurements		c. Units:	—
		Inches	(1)
8. Height (shoes off)		Centimeters	(2)
a. 1st measurement:b. 2nd measurement:	<u> </u>	11. Hip (standing, at fullest part of waist measurements until you ments within 4 in (10.2 cm) of	have two measure-
	•	a. 1st measurement:	
c. Units:	<u> </u>		•
Inches	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	b. 2nd measurement:	
Centimeters	(2)		•
		c. Units:	
		Inches	(1)
		Centimeters	$\begin{pmatrix} & & & \\ & & & \end{pmatrix}$

12. Temperature (oral or other as a	ppropriate for age)	D. Administrative inform	nation	
a. Degrees:	·	17. Study Physician PIN	:	
b. Scale:Fahrenheit:Centigrade:	(₁) (₂)	18. Study Physician sign	ature:	
13. Blood pressure		19. Clinical Coordinator	PIN:	
a. Systolic:		20. Clinical Coordinator	signature:	
b. Diastolic:				
14. Resting radial pulse:	beats/minute	21. Date form reviewed:		
15. Respiratory rate:	breaths/minute	day	mon	year
C. Focused liver signs				
16. Abnormality (check all that app	oly)			
a. Ascites:	(1)			
b. Asterixis:	(1)			
c. Contractures:	(1)			
d. Hepatic encephalopathy:	(1)			
e. Hepatocellular carcinoma:	(1)			
f. Hepatomegaly:	(1)			
If Yes, span from right midce	lavicular line:			
	cm			
g. Hepatopulmonary syndrome	: (1)			
h. Hepatorenal syndrome:	(1)			
i. Jaundice:	(1)			
j. Muscle wasting:	(1)			
k. Palmar erythema:	(1)			
l. Pedal edema:	(1)			
m. Portal hypertension:	(1)			
n. Spider angiomata:	(1)			
o. Splenomegaly:	(1)			
p. Other, (specify):	(1)			
q. None of the above	(1)			

RG - Registration

Purpose: To register patients as candidates for enrollment in This is the first form completed for a NAFLD Database pakeyed, before any other NAFLD Database forms.		
When: At first screening visit (s1).		
Administered by: Clinical Coordinator.		
Respondent: Patient and parent (if patient is age 17 or your Instructions: Use Flash Cards as instructed. Do not assign a NASH CRN study.	- - /	
A Contain notions and visit identification	12 Ethnia actorowy (chan the nationt/navout Elach	
A. Center, patient and visit identification 1. Center ID:	12. Ethnic category (show the patient/parent Flash Card #1 and ask the respondent to pick the category that describes the patient best; check only one):	
	Hispanic or Latino or Latina (1)	
2. Patient ID:	Not Hispanic, not Latino, not Latina (2)	
	14. — 14.	
3. Patient code:	14.	
	13. What describes your Hispanic, Latino, or	
4. Visit date:	Latina origin best (show the patient/parent Flash Card #1 and ask the respondent to pick the sub-	
	category that best describes their Hispanic, Lat-	
day mon year	ino, or Latina origin; check only one):	
5. Visit code: _s_1	Mexican (1)	
	Puerto Rican (₂)	
6. Form & revision:r _ g _ 1	Cuban (3)	
	South or Central American (4)	
7. Study: NAFLD Database 1	Other Spanish culture or origin (5)	
B. Consent	specify	
8. Has the patient (or patient's guardian) signed the NAFLD Database informed consent statement:	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 patient	c. Black, African American, Negro, or Haitian:	
9. Date of birth:	d. Native Hawaiian or other Pacific Islander: (1)	
day month year	e. White:	
Record 4-digit year for date of birth.	f. Patient refused: (1)	
10. Age at last birthday:	15. In what country was the patient born <i>(check only one)</i> :	
11. Gender:	Continental US (includes Alaska) or Hawaii (1)	
Male (,)	Other, (specify):	

Female

specify

16. Highest educational level achieved by patient (show the patient/parent Flash Coask the respondent to pick the categor scribes 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 # the respondent to pick the category that the patient's combined household incomplete.	6 and descr	ibes
	Never attended school	(0)		check only one):	ine o	esi,
	Kindergarten, pre kindergarten, or	,			Less than \$15,000	(1)
	younger	(1)		\$15,000 - \$29,999	(
	Grades 1 to 5	(2)		\$30,000 - \$49,999	(.)
	Grades 6-8	(3)		\$50,000 or more	(2) 3) 4)
	Grades 9-11	(4)		\$50,000 of more	(4)
	Completed high school	(₅)	23.	Is the patient under age 18:		
	Some college or post high school	,	,		$\binom{\mathrm{Yes}}{1}$	(1	No \
	education or training	(6)			28.	2 <i>)</i>
	Bachelor's degree or higher	(₇)		<u>l-</u>	28.	_
	_	20.	No 2) 	24.	Current age of patient's mother, stepmother, or female guardian (show patient/parent Flash Card #7; cone): Not applicable (mother is deceased or patient has no stepmother or female	heck o	only
18.	What is the patient's current occupation	1:			guardian)	(0
					19 or younger	(1)
	specify occupation				20-29 years	(
10	About how many hours does the patient	4			30-39 years	Ò	2) 3)
17.	work each week:	l			40-49 years	(4)
		# hour	S		50-59 years	(₅)
20	Which of the following categories best				60 years or older	(5) 6)
20.	characterizes the patient's occupational history (show the patient/parent Flash and ask the respondent to pick the cat describes the patient best; check only o Never employed	h Card egory		25.	Highest educational level achieved by patient's mother, stepmother, or female guardian (show patient/parent Flash C education of mother or female guardiknown, record as "n"; check only one):	ard #8	8; if
	Laborer	(1)		Never attended school	()
	Clerical	(2)		Did not complete high school		0)
	Professional	(3)		Completed high school		1))
	Homemaker	(4)		Some college or post high school	(2)
	Other, (specify):	(5)		education or training	(3)
					Bachelor's degree or higher	Ò	.)
	specify				Zuonoror o degree or migner	(4)
21.	Marital status of the patient (show the patient/parent Flash Card # the respondent to pick the category that the patient best; check only one):						
	Single, never married	(1)				
	Married or living in marriage-like relationship	(
	Separated, divorced, or annulled	(₂)				
	Widowed	(3)				
	widowed	(4)				

26.	Current age of patient's father, stepfather, or male guardian (show patien Flash Card #7; check only one):	ent/pa	rent	E. Previous registration in a NASH CRN study29. Has the patient ever been assigned an ID
	Not applicable (father is deceased or			number in a NASH CRN study:
	patient has no stepfather or male	(,	$\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$
	guardian)	(0)	I
	19 or younger	(1)	33.
	20-29 years	(2)	30. In which NASH CRN studies has the
	30-39 years	(3)	patient previously been registered (check all that
	40-49 years	(4)	apply)
	50-59 years	(₅)	a. PIVENS: (1)
	60 years or older	(6)	b. TONIC: (₁)
27.	Highest educational level achieved by patient's father, stepfather, or male guardian (show patient/parent Flash Coeducation of father or male guardian is	ard #8 unkno	8; if own,	c. Other, (specify): specify
	record as "n"; check only one):	(`	31. ID Number previously assigned to patient (record
	Never attended school	(0)	patient ID in item 2):
	Did not complete high school	(1)	
	Completed high school	(2)	22 Code previously essigned to notice (uses and ma
	Some college or post high school education or training	(3)	32. Code previously assigned to patient (record patient code in item 3):
	Bachelor's degree or higher	(4)	
	clinic staff should pick the best descript source of the patient) Source of patient (check only one): Bariatric surgery clinic Current patient of NASH CRN investigator Diabetes clinic GI/liver clinic HMO-based Internal medicine clinic Lipid disorders clinic Liver transplant clinic Obesity clinic Pediatric clinic Pediatric weight disorders clinic Self referral Other, (specify):	(((((((((((((((((((o1) 02) 03) 04) 05) 06) 07) 08) 09) 10) 11) 12) 13) 14)	F. ID assignment (If a STOP condition was checked in section B, the patient is ineligible and a Patient ID should not be assigned. If the patient was previously registered in a NASH CRN study, a new ID number should not be assigned.) 33. Place ID label below and record Patient ID in item 2 and patient code in item 3. CCCC ####, zzz
				36. Date form reviewed:
	specify			
				day mon year