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.

DR - Death Report

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

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

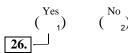
Administered by: Study Physician and Clinical Coordinator.

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

A. Center, patient, and visit identification			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 k have and your best medical judgmen acterize the cause of death; check o	ıt to best char-			
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							

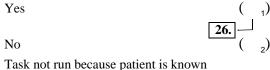
F. Eligibility check

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.

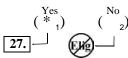
24. Were any STOP's or ineligible conditions other than "missing Form ED" identified by the Enrollment Task:



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.

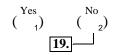
11. Has the patient had an upper abdominal imaging study since the last visit:

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

*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 smoki	ng			r. Hepatic encephalopathy:	(1)
16. Since the last visit, have you smoked				s. Portal hypertension:	(1)
tobacco cigarettes regularly ("No" means		,		t. Hepatorenal syndrome:	(1)
smoked less than 1 day	per week on averag Yes	<i>(e):</i> N	lo	u. Hepatopulmonary syndrome:	(1)
	(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	l 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)
	(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 (check all that app	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 (<i>check all that apply</i>):			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,	,		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)			
l. Other, (specify):	(1)	j. Other, (specify):	(1)
m. None of the above:	(1)	k. None of the above:		1)
any antiobesity medications (check all thata. Dexfenfluramine hydrochloride (Redux):	л арр (1).	containing acetaminophen medication in the past 6 months (check all that apply)		
b. Fenfluramine hydrochloride		·	a. Darvocet:	(1)
(Pondimin):	(1)	b. Esgic - Plus:	(1)
c. Methamphetamine hydrochloride	(`	c. Fioricet:	(1)
(Desoxyn, Gradumet):	(1)	d. Lorcet:	(1)
d. Orlistat (Xenical):	(1)	e. Lortab:	(1)
e. Phendimetrazine tartrate (Adipost, Bontril):	(1)	f. Norco:	(1)
f. Phentermine hydrochloride (Adipex,	`	17	g. Percocet:	(1)
Fastin, Ionamin, Teramine):	(1)	h. Talacen:	(1)
g. Sibutramine hydrochloride	,	,	i. Tylenol #3:	(1)
monohydrate (Meridia):	(1)	j. Tylenol #4:	(1)
h. Other, (specify):	(1)	k. Tylox:	(1)
			l. Vicodin:	(1)
i. Other, (specify):	(1)	m. Wygesic:	(1)
			n. Other, (specify):	(1)
j. None of the above:	(1)	, ()//-	`	1/
			• None of the above:	(1)

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

34. Since the last visit, has the patient taken any systemic corticosteroids (<i>check all that apply</i>):		
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):

l. None of the above:

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): c. Budesonide (Pulmicort, Rhinocort):	(1)	d. Betaine (Cystadane):	(₁)
		(1)	e. Calcium (any form):	(, 1)
	d. Fluticasone propionate (Flonase, Flovent):	(1)	f. Carnitine (any form):	(1)
	e. Loratadine (Claritin):	(1)	g. Chondroitin (any form):	(1)
	f. Mometasone furoate (Nasonex):g. Triamcinolone acetonide (Azmacort,	(1)	h. Choline + methionine + betaine + adenosine + pyridoxine (Epocler):	(1)
	Nasacort):	(1)	i. Cod liver oil:	(1)
	h. Other, (specify):	(1)	j. Coenzyme Q:	(1)
				k. Dichloroacetate:	(1)
	i. Other, (specify):	(1)	l. Echinacea:	(1)
				m. Fish oil (any form):	(1)
	j. None of the above:	(1)	n. Flax seed oil:	(1)
			17	o. Garlic:	(1)
38.	Since the last visit, has the patient taken a multivitamin regularly:			p. Ginkgo biloba:	(1)
	Yes (1)	(1	No 2)	q. Glucosamine (any form):	(1)
	(1)	(2)	r. Lecithin:	(1)
39.	Since the last visit, has the patient taken vitamins other than multivitamins:			s. Magnesium:	(1)
	Yes	(No		t. Milk thistle:	(1)
	(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):	(1)
				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		

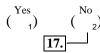
hypertension (specify):

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
------------------	---------------

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

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:	<u></u>	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

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 be 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	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
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)			

BC - Blood Collection for DNA

Purpose: Document the collection of whole blood for shipment to NIDDK Genetics Repository at Rutgers University for DNA extraction. Complete this form only if the patient signed the consent for genetic research.

When: Visit s2 and as needed during followup (during followup, use the visit code of the followup visit that is open). **By whom**: Clinical Coordinator and laboratory personnel responsible for collection of whole blood.

Instructions: (1) Fill two 10 mL EDTA vacutainer tubes with whole blood. (2) Pack and ship the whole blood in the EDTA tubes to the NIDDK Genetics Repository at Rutgers University on the same day blood is collected. Ship at ambient room temperature. Ship whole blood in the specimen shippers supplied by the NIDDK Genetics Repository.

A. Center, patient and visit identification	10. Date and time of blood draw
1. Center code:	a. Date:
2. Patient ID:	day mon year b. Time:
3. Patient code:	. Time.
4. Date of visit:	hour minute am 1 pm 11. Number of 10 mL EDTA tubes:
day mon year 5. Visit code:	12. Form copy of tube labels:
6. Form & revision: <u>b c 1</u>	NAFLD DB Form BC
7. Study: NAFLD Database 1	Pt: ccc- 9999, xyz Gender
B. Check on consent	Age, yrs.: XX
8. Did the patient/parent consent/assent to blood draw for DNA extraction:	
$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{*}_{2}$	13. Phlebotomist:
* You cannot proceed until you get consent.	print name
	D. Administrative information
C. Specimen for Genetics Repository Attach ID labels to two 10mL EDTA tubes and fill	14. Clinical Coordinator PIN:
each with whole blood; invert each tube gently 6 times to mix blood with additives; keep tubes at room temperature until the same day shipment to	15. Clinical Coordinator signature:
the NIDDK Genetics Repository.9. Was blood collected for the NIDDK	16. Date form reviewed:
Genetics Repository:	day mon year
Yes (1)	
No, $(specify)$:	
specify	

14. —

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 f is checked for an item, use caution. If the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database. If f is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database. The form should not be keyed to the data system, but the form should be retained; set aside with forms for other patients who started screening, but were found to be ineligible. A. Center, visit, and patient identification 10. Do any of the patient's first degree relatives (parent, brother, sister, child) 1. Center ID: have cirrhosis: 2. Patient ID: 3. Patient code: 11. If yes, is the cause of the cirrhosis unknown (cryptogenic): **4.** Visit date (date this form is initiated): 12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2): 5. Visit code: <u>s</u> 1 Yes <u>b</u> <u>g</u> <u>1</u> **6.** Form & revision: No Don't know 7. Study: NAFLD Database 1 13. Do any of the patient's first degree relatives (parent, brother, sister, child) **B.** Family history have obesity: Yes **8.** Do any of the patient's first degree relatives (parent, brother, sister, child) No have liver disease: Don't know 14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat: **9.** If yes, characterize the liver disease(s) (check all that apply) No a. Alcohol related liver disease: 1) Don't know **b.** Viral hepatitis: 1) 15. Do any of the patient's first degree **c.** Alpha-1 antitrypsin deficiency: relatives (parent, brother, sister, child) **d.** Wilson's disease: 1) have a problem with cholesterol or blood fat: **e.** Glycogen storage disease: Yes f. Iron overload: No **g.** Fatty liver disease (NAFLD, NASH): 1) Don't know

h. Type of liver disease unknown:

C. NAFLD history

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

_		_
day	mon	year

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

a. Symptoms for liver disease: (1)
---	----

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

_	T 1 1.1	(
a.	Liver biopsy:	(1

specify

19. Has the patient ever had a liver biopsy:

*Complete the Liver Biopsy Materials Documentation (SD) form for the most recent liver biopsy, unless the patient will have another biopsy during screening.

- **20.** Dates of liver biopsy (in reverse chronological order)
 - **a.** Date of most recent liver biopsy:

		
day	mon	year

b. Date of 2nd most recent liver biopsy:

_		=
day	mon	year

c. Date of 3rd most recent liver biopsy:

=		_
day	mon	year

21. Will the patient have a biopsy during screening:

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

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

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

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

*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 (

Up sharply (gained a lot in a brief interval)
$$($$
 $_3)$

Down sharply (lost a lot in a brief interval) (
$$_5$$
)

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

lbs	

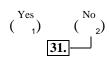
26. What is the most the patient has ever weighed:

lbs

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

age in years

28. Is the patient age 18 or older:



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

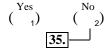
31. Does the patient weigh more than he/she did one year ago:



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



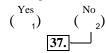
33. Does the patient weigh less than he/she did one year ago:



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:



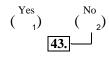
36. Which did the patient try to do (*check only one*):

Gain weight (
Lose weight (

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:

Never

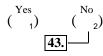
In the past but not anymore

Currently smokes cigarettes

(1)

(2)

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:

years

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

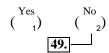
years

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

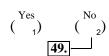
cigarettes/day

F. Menstrual history

43. Is the patient female:



44. Has menarche occurred:



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

age in years

46. Characterize the menstrual history in the	n. Bleeding from varices:	(1)
past 5 years (check only one):	o. Other gastrointestinal bleeding:	(1)
Regular periods (1)	p. Ascites:	(1)
Irregular periods (2) Rare periods (3)	q. Edema:	(1)
No periods (4)	r. Hepatic encephalopathy:	(1)
1 to periods	s. Portal hypertension:	(1)
47. Is patient post-menopausal: Yes No	t. Hepatorenal syndrome:	(1)
$\binom{1}{1}$ $\binom{1}{2}$	u. Hepatopulmonary syndrome:	(1)
49.	v. Short bowel syndrome:	. (()
48. What was the patient's age at menopause:	/	$\hat{\mathbf{c}}$	′ا ل
age in years	w. Hemophilia (bleeding disorder):		₁)
G. Medical history (means Caution; condition is exclusionary if study physician agrees with diagnosis)	x. Systemic autoimmune disorder such a rheumatoid arthritis or systemic lupus		1)
49. Has the patient ever been diagnosed with	y. Endocrine disease (hormonal abnormality):	(1)
and treated for any of the following (check all that apply; source of information can be interview and/or chart review)	z. Hepatocellular carcinoma:	$\hat{\mathbf{c}}$	₁)
a. Diabetes type 1: (₁)	aa. Other malignancy (cancer):	(1)
b. Diabetes type 2: (1)	ab. Peripheral neuropathy:	(1)
c. Gestational diabetes	ac. Seizure disorder or epilepsy:	(1)
(diabetes of pregnancy): (1)	ad. Drug allergies:	(1)
d. Hepatitis B:	ae. Hypothyroidism:	(1)
e. Hepatitis C:	af. Hypertension:	(1)
C Tropando e.	ag. Cerebrovascular disease:	(1)
f. Autoimmune hepatitis:	ah. Dysbetalipoproteinemia:	$\Diamond \frac{1}{2}$	1)
g. Autoimmune cholestatic liver disorder (PBC or PSC):	ai. Hyperlipidemia (high cholesterol, high triglycerides):	<u>C </u>	1)
h. Wilson's disease:	aj. Pancreatitis:	(1)
$\langle C \rangle$	ak. Cholelithiasis:	(1)
i. Alpha-1-antitrypsin (A1AT) deficiency: (1)	al. Coronary artery disease:	(1)
C -	am. Elevated uric acid such as gout:	(1)
j. Iron overload:	an. Kidney disease:	(1)
<u>C</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)	H. Medication use		
	as. Myositis:	(1)	54. Has the patient used any antidiabetic		
	at. Major depression:	(1)	medications in the past 6 months		
	au. Schizophrenia:	(1)	(check all that apply):	,	,
	av. Bipolar disorder:	(1)	a. Acarbose (Precose):	(1)
	aw. Obsessive compulsive disorder:	(1)	b. Acetohexamide (Dymelor):	(1)
	ax. Severe anxiety or personality			c. Chlorpropamide (Diabinese):	(1)
	disorder:	(1)	d. Glimepiride (Amaryl):	(1)
	ay. None of the above:	(1)	e. Glipizide (Glucotrol, Glucatrol XL):	(1)
50.	Has the patient ever had surgery for any of the following (check all that apply)	•		f. Glyburide (Micronase, DiaBeta, Glynase):	(1)
		(`	g. Insulin:	(1)
	a. Stapling or banding of the stomach:	<u>c</u>	」 ¹ /	h. Metformin (Glucophage, Glucophage XR):	(1)
	b. Jejunoileal (or other intestinal)	()	i. Miglitol (Glycet):	(1)
	bypass:	\Diamond	」 」	j. Nateglinide (Starlix):	(1)
	c. Biliopancreatic diversion:	<u> </u>	.)	k. Pioglitazone (Actos):	(1)
	/ Smopanereane arversion	$\langle c \rangle$	」 17	l. Repaglinide (Prandin):	(1)
	d. Other GI or bariatric surgery (<i>specif</i>)	·): (,)	m. Rosiglitazone (Avandia):	(1)
	3 3 (1 3)	, (1/	n. Tolazamide (Tolinase):	(1)
	e. None of the above:	(o. Tolbutamide (Orinase):	(1)
	c. None of the above.	(1/	p. Other, (specify):	(1)
51.	Organ, limb, or bone marrow transplant					
	a. Has the patient ever received a liver transplant:			q. None of the above:	(1)
	Yes (Yes)		No ₂)	55. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 6 months (<i>check all that apply</i>):		
	b. Has the patient ever received any other organ, limb, or bone marrow			a. Chlordiazepoxide (Librium):	(1)
	transplant:			b. Clorazepate dipotassium (Tranxene):	(1)
	$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$	1	No 2)	c. Diazepam (Valium):	(1)
52			-	d. Disulfiram (Antabuse):	(1)
54.	Has the patient received total parenteral nutrition (TPN) in the past 2 years:			e. Hydroxyzine pamoate (Vistaril):	(1)
	Yes (Yes	(1	No 2)	f. Naltrexone hydrochloride (Revia):	(1)
	(1)	(2/	g. Other, (specify):	(1)
53.	Is the patient currently undergoing evaluation for bariatric surgery:					
	$\binom{\operatorname{Yes}}{1}$	1	No 2)	h. None of the above:	(1)

56.	Has the patient taken any antihyperlipidemic medications in the past 6 months (<i>check all that apply</i>):			non-ster aspirin o	patient taken any pain relieving, oidal anti-inflammatory, or containing medications in the past		
	a. Atorvastatin (Lipitor):	(1)		s (check all that apply):		
	b. Colestipol hydrochloride (Colestid):	(1)	a. Aceta	nminophen (Tylenol):	(1)
	c. Clofibrate (Abitrate, Atromid-S,			b. Aspin	rin - 325 mg:	(1)
	Claripex, Novofibrate):	(1)	c. Aspir	rin - 81 mg:	(1)
	d. Gemfibrozil (Gen-Fibro, Lopid):	(1)	d. Cele	coxib (Celebrex):	(1)
	e. Fenofibrate (Tricor):	(1)	e. Ibupr	ofen (Advil, Motrin):	(1)
	f. Fluvastatin sodium (Lescol):	(1)	f. Indon	nethacin (Indocin):	(1)
	g. Lovastatin (Mevacor):	(1)	g. Napr	oxen (Aleve, Naprosyn):	(1)
	h. Nicotinic acid (Niaspan):	(1)	h. Rofe	coxib (Vioxx):	(1)
	i. Pravastatin sodium (Pravachol):	(1)	i. Other	, (specify):	(1)
	j. Rosuvastatin (Crestor):	(1)				
	k. Simvastatin (Zocor):	(1)	j. Other	, (specify):	(1)
	1. Other, (specify):	(1)				·
				k. Othe	r, (specify):	(1)
	m. None of the above:	(1)		, (- <u>r</u> 9)/-	`	1/
57.	Has the patient taken any antiobesity medications in the past 6 months (check all that apply):			59. Has the	of the above: patient taken any strong opiates ng acetaminophen medication in	(1)
	a. Dexfenfluramine hydrochloride (Redux):	(1)	the past	6 months (check all that apply)	,	
	b. Fenfluramine hydrochloride			a. Darv		(1)
	(Pondimin):	(1)	b. Esgio		(1)
	c. Methamphetamine hydrochloride (Desoxyn, Gradumet):	(1)	c. Fiorio		(1)
	d. Orlistat (Xenical):	(1)	d. Lorce		(1)
		(1)	e. Lorta		(1)
	e. Phendimetrazine tartrate (Adipost, Bontril):	(1)	f. Norce):	(1)
	f. Phentermine hydrochloride (Adipex,			g. Perco		(1)
	Fastin, Ionamin, Teramine):	(1)	h. Talac	cen:	(1)
	g. Sibutramine hydrochloride	(`	i. Tylen	ol #3:	(1)
	monohydrate (Meridia):	(1)	j. Tylen	ol #4:	(1)
	h. Other, (specify):	(1)	k. Tylo	x:	(1)
				l. Vicod	lin:	(1)
	i. Other, (specify):	(1)	m. Wyg	gesic:	(1)
				n. Othe	r, (specify):	(1)
	j. None of the above:	(1)				
				o. None	of the above:	(1)

60.	Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal medications in the past 6 months (check apply):		that
	a. Cimetidine (Tagamet):	(1)
	b. Esomeprazole magnesium (Nexium):	(1)
	c. Famotidine (Pepcid):	(1)
	d. Lansoprazole (Prevacid):	(1)
	e. Nizatidine (Axid):	(1)
	f. Omeprazole (Prilosec):	(1)
	g. Ranitidine (Zantac):	(1)
	h. Ranitidine bismuth citrate (Tritec):	(1)
	i. Antacids, (specify):	(1)
	j. Other, (specify):	(1)
	k. Other, (specify):	(1)
	l. None of the above:	(1)
61.	Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months (check all that apply):		
	a. Clopidogrel (Plavix):	(1)
	b. Dipyridamole:	(1)
	c. Heparin:	(1)
	d. Ticlopide (Ticlid):	(1)
	e. Warfarin (Coumadin):	(1)
	f. Other, (specify):	(1)
	g. Other, (specify):	(1)
	h. None of the above:	(1)

62. Has the patient taken any systemic corticosteroids in the past 6 months (<i>check all that apply</i>):		
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)
1. None of the above:	(1)

ac. None of the above:	(1)	v. None of the above:	(1
ab. Other, (specify):	(1)	u. Other, (specify):	(1
aa. Other, (specify):	(1)	<u> </u>	,	1
z. Verapamil (Calan):	(1)	t. Other, (specify):	(1
y. Valsartan (Diovan):	(1)	s. Tamoxifen (Nolvadex):	(1
x. Timolol maleate (Blocadren):	(1)	r. Raloxifene (Evista):	(1
w. Terazosin (Hytrin):	(1)	q. Progesterone (Prometrium):	(1
v. Quinapril (Accupril):	(1)	p. Oxymetholone (Anadrol):	(1
u. Propranolol (Inderal):	(1)	o. Oxandrolone (Oxandrin):	(1
t. Perhexiline maleate:	(1)	Ovral, Tri-Levlen, Triphasil, Trivora, Zovia):	(
s. Nifedipine (Adalat, Procardia):	(1)	Ortho-Novum, Ortho Tri-Cyclen,		
r. Metoprolol (Lopressor):	(1)	Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen,		
q. Losartan potassium with hydrochlorothiazide (Hyzaar):	(1)	Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin,		
p. Losartan potassium (Cozaar):	(1)	n. Oral contraceptives (Alesse, Demulen,	`	
o. Lisinopril (Prinivil, Zestril):	(1)	m. Norgestrel (Ovrette):	(
(Dyazide):	(1)	Decanoate, Kabolin): l. Norethindrone (Micronor):	(
n. Hydrochlorothiazide + triamterene	(1)	k. Nandrolone (Deca-Durabolin, Hybolin		
m. Hydrochlorothiazide (Esidrix, HydroDIURIL):	(`	j. Methyltestosterone (Android):	(
l. Furosemide (Lasix):	(1)	i. Megestrol (Megace):	(
k. Felodipine (Plendil):	(1)	h. Medroxyprogesterone (Cycrin, Provera):	(
j. Enalapril (Vasotec):	(1)	g. Levonorgestrel (Norplant):	(
i. Doxazosin (Cardura):	(1)	Halotestin):	(
h. Diltiazem (Cardizem):	(1)	f. Fluoxymesterone (Android-F,		
	1)	e. Ethinyl estradiol (Estinyl):	(
f. Clonidine (Catapres):	(1)	d. Estradiol (Estrace):	(
e. Captopril (Capoten):	(1)	c. Esterified estrogen (Estratab, Menest):	(
d. Benazepril (Lotensin):	(1)	b. Diethylstilbestrol and methyltestosterone (Tylosterone):	(
b. Amlodipine besylate (Norvasc):c. Atenolol (Tenormin):	(1) 1)	(Premarin/Prempro):	(
a. Amiodarone (Pacerone):	(1)	a. Conjugated estrogen		
Has the patient taken any cardiovascular or antihypertensive medications in the past 6 months (check all that apply):	(,	64. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months (<i>check all that apply</i>):		

65.	Has the patient taken any allergy or asthma medications in the past 6 months			69. Has the patient taken any supplements in the past 6 months (<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):	(1)
	d. Fluticasone propionate (Flonase, Flovent):	(1)	f. Carnitine (any form):	(1) 1)
	e. Loratadine (Claritin):	(1)	g. Chondroitin (any form):	(1) 1)
	f. Mometasone furoate (Nasonex):	(1) 1)	h. Choline + methionine + betaine +	(1)
	g. Triamcinolone acetonide (Azmacort,	(1)	adenosine + pyridoxine (Epocler):	(1)
	Nasacort):	(1)	i. Cod liver oil:	(1)
	h. Other, (specify):	(1)	j. Coenzyme Q:	(1)
				k. Dichloroacetate:	(1)
	i. Other, (specify):	(1)	l. Echinacea:	(1)
		`	1/	m. Fish oil (any form):	(1)
	j. None of the above:	(1)	n. Flax seed oil:	(1)
	j. I voice of the doove.	(1/	o. Garlic:	(1)
66.	Has the patient taken a multivitamin			p. Ginkgo biloba:	(1)
	regularly in the past 6 months:	1	No .	q. Glucosamine (any form):	(1)
	$\binom{\mathrm{Yes}}{1}$	(2)	r. Lecithin:	(1)
67. Has the patient taken vitamins other than				s. Magnesium:	(1)
	multivitamins in the past 6 months: (Yes (1)	,	No.	t. Milk thistle:	(1)
		(2)	u. N-acetyl-cysteine:	(1)
	69		J	v. Potassium (any form):	(1)
68.	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):	(1)
				act outer, (specify).	(1/
				ad. Other, (specify):	(1)

ae. None of the above:

year

70.	Has patient taken any of the following medications or other supplements/medications in the past 6 months (record all other supplements/medications):							
	a. Demeclocycline (Declomycin):							
	b. Divalproex (Depakote):							
	c. Doxycycline (Monodox):							
	d. Isotretinoin (Accutane):	(1)					
	e. Levothyroxine (Levoxyl, Synthroid):	(1)					
	f. Liothyronine (Cytomel):	(1)					
	g. Methotrexate (Rheumatrex):	(1)					
	h. Minocycline (Dynacin, Minocin):	(1)					
	i. Oxytetracycline (Terramycin):	(1)					
	j. Penicillamine (Cuprimine, Depen):							
	k. Tetracycline (Achromycin):l. Trientine hydrochloride (Syprine):		1)					
			1)					
	m. Ursodeoxycholic acid (Actigall, Urso, Ursodiol):	(1)					
	n. Valproate sodium (Depacon):	(1)					
	o. Valproic acid (Depakene):	(1)					
	p. Other, (specify):	(1)					
	q. Other, (specify):	(1)					
	r. Other, (specify):	(1)					
	s. Other, (specify):	(1)					
	t. Other, (specify):	(1)					
	u. None of the above:	(1)					

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

mon

day

When: Visit s1.

BG - Baseline History

Purpose: To collect baseline history information about the patient.

Administered by: Clinical Coordinator, reviewed by Study Physician. **Respondent**: Patient or patient's parent. **Instructions**: Collect information by interview or chart review. If f is checked for an item, use caution. If the physician agrees with the diagnosis, the patient is ineligible for the NAFLD Database. If f is checked for an item, the patient is ineligible and cannot enroll in the NAFLD Database. The form should not be keyed to the data system, but the form should be retained; set aside with forms for other patients who started screening, but were found to be ineligible. A. Center, visit, and patient identification 10. Do any of the patient's first degree relatives (parent, brother, sister, child) 1. Center ID: have cirrhosis: 2. Patient ID: 3. Patient code: 11. If yes, is the cause of the cirrhosis unknown (cryptogenic): **4.** Visit date (date this form is initiated): 12. Do any of the patient's first degree relatives (parent, brother, sister, child) have diabetes (Type 1 or Type 2): 5. Visit code: <u>s</u> <u>1</u> ___ _ Yes <u>b</u> <u>g</u> 2 **6.** Form & revision: No Don't know 7. Study: NAFLD Database 1 13. Do any of the patient's first degree relatives (parent, brother, sister, child) **B.** Family history have obesity: Yes **8.** Do any of the patient's first degree relatives (parent, brother, sister, child) No have liver disease: Don't know 14. Do any of the patient's first degree relatives (parent, brother, sister, child) have atrophy of body fat: **9.** If yes, characterize the liver disease(s) (check all that apply) No a. Alcohol related liver disease: 1) Don't know **b.** Viral hepatitis: 1) 15. Do any of the patient's first degree c. Alpha-1 antitrypsin deficiency: relatives (parent, brother, sister, child) **d.** Wilson's disease: 1) have a problem with cholesterol or blood fat: **e.** Glycogen storage disease: Yes f. Iron overload: No **g.** Fatty liver disease (NAFLD, NASH): 1) Don't know **h.** Type of liver disease unknown:

C. NAFLD history

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

_		_
day	mon	year

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

a. Symptoms for liver disease:	(1)

b. Result of being evaluated for another illness: (1)

c. During a routine or insurance physical	
examination:	(

- **d.** Blood donation: (1)
- e. Other (specify):

speci	fy

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

a. Liv	er biopsy:	(1)
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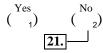
d. Other (<i>specify</i>):	(

specify

Do at a distant	1.
Does the patient have one or mo	
biopsies done prior to registration	on in the

Database that you want evaluated for the Database:

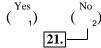
19.



- **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):

<u></u> _		
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):

_		
day	mon	year

21. Will the patient have a biopsy during screening:

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

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

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

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

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

D. Weight history

23. What was the patient's birthweight:

______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

Up gradually

Up sharply (gained a lot in a brief interval)

Down gradually

Down sharply (lost a lot in a brief interval)

5

No or minimal change (6)

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

nationt has aver

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

lbs

1hs

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

age in years

28. Is the patient age 18 or older:

Yes (No 2)

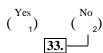
29. What is the least the patient has ever weighed since age 18:

lbs

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

age in years

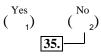
31. Does the patient weigh more than he/she did one year ago:



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

lbs

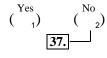
33. Does the patient weigh less than he/she did one year ago:



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:



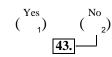
36. Which did the patient try to do (check only one):

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:



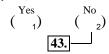
38. Have you ever smoked tobacco cigarettes:

Never (1)

In the past but not anymore (2)

Currently smokes cigarettes (2)

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:

years

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

years

42. On the average of the entire time you smoked cigarettes, how many cigarettes	e. Hepatitis C:	(1)
did you smoke per day:	f. Autoimmune hepatitis:	(1)
cigarettes/day	g. Autoimmune cholestatic live (PBC or PSC):	er disorder
F. Menstrual history		<u></u>
43. Is the patient female:	h. Wilson's disease:	()
(₁) (49.	i. Alpha-1-antitrypsin (A1AT)	deficiency: (1)
44. Has menarche occurred:	j. Iron overload:	<u>(</u> 1)
(₁) (k. Drug induced liver disease:	(1)
	l. Gilbert's syndrome:	(1)
45. What was the patient's age at menarche: age in year	m. Esophageal or gastric varice endoscopy:	es on (₁)
46. Characterize the menstrual history in the	n. Bleeding from varices:	(1)
past 5 years (check only one):	o. Other gastrointestinal bleeding	ng: $\binom{1}{1}$
Regular periods (p. Ascites:	(1)
Irregular periods (q. Edema:	(1)
Rare periods (3) r. Hepatic encephalopathy:	(1)
No periods (s. Portal hypertension:	(1)
47. Is patient post-menopausal:	t. Hepatorenal syndrome:	(1)
Yes (u. Hepatopulmonary syndrome	: (₁)
49.	v. Short bowel syndrome:	(1)
48. What was the patient's age at menopause: age in year	w. Hemophilia (bleeding disord	der): (
G. Medical history (means Caution; condition exclusionary if study physician agrees with di		
nosis)49. Has the patient ever been diagnosed with	y. Endocrine disease (hormonal abnormality):	(1)
and treated for any of the following (check all that apply; source of information can be interview and/or chart review)	z. Hepatocellular carcinoma:	<u>(</u> 1)
a. Diabetes type 1:	aa. Other malignancy (cancer).	: (1)
b. Diabetes type 2:	ab. Peripheral neuropathy:	(1)
c. Gestational diabetes	ac. Seizure disorder or epilepsy	y: (₁)
(diabetes of pregnancy):	ad. Drug allergies:	(1)
d. Hepatitis B:	ae. Hypothyroidism:	(1)

	af. Hypertension:	(1)	51. Organ, limb, or bone marrow transplant		
	ag. Cerebrovascular disease:	(1)	a. Has the patient ever received a liver		
	ah. Dysbetalipoproteinemia:	<u>(</u>	(,	transplant:	1 (1 K	√o 2)
	ai. Hyperlipidemia (high cholesterol, high triglycerides):	()	—(L)	g	
	aj. Pancreatitis:	(1) 1)	b. Has the patient ever received any other organ, limb, or bone marrow		
	ak. Cholelithiasis:	(1)	transplant:	1	No
	al. Coronary artery disease:	(1)	$\binom{\mathrm{Yes}}{1}$	(No 2)
	am. Elevated uric acid such as gout:	(1)	52. Has the patient received total parenteral		
	an. Kidney disease:	(1)	nutrition (TPN) in the past 2 years:		
	ao. Polycystic ovary syndrome:	(1)	(Yes (1)	1	No 2)
	<pre>ap. Sleep apnea (not breathing during sleep):</pre>	(1)	53. Is the patient currently undergoing		
	aq. Dermatologic disorders:	(1)	evaluation for bariatric surgery: Yes	1	No
	ar. Myopathy:	(1)	$\binom{\operatorname{Yes}}{1}$	(2)
	as. Myositis:	(1)	H. Medication use		
	at. Major depression:	(1)	54. Has the noticest used any outidishetic		
	au. Schizophrenia:	(1)	54. Has the patient used any antidiabetic medications in the past 6 months		
	av. Bipolar disorder:	(1)	(check all that apply):		
	aw. Obsessive compulsive disorder:	(1)	a. Acarbose (Precose):	(1)
	ax. Severe anxiety or personality	,		b. Acetohexamide (Dymelor):	(1)
	disorder:	(1)	c. Chlorpropamide (Diabinese):	(1)
	ay. None of the above:	(1)	d. Glimepiride (Amaryl):	(1)
50.	Has the patient ever had surgery for an	ıy		e. Glipizide (Glucotrol, Glucatrol XL):	(1)
	of the following (check all that apply)		`	f. Glyburide (Micronase, DiaBeta, Glynase):	(1)
	a. Stapling or banding of the stomach:	6	」 」	g. Insulin:	(1)
	b. Jejunoileal (or other intestinal) bypass:	()	h. Metformin (Glucophage, Glucophage XR):	(1)
	by pass.	6	」 ¹ /	i. Miglitol (Glycet):	(1)
	c. Biliopancreatic diversion:	<u> </u>	.)	j. Nateglinide (Starlix):	(1)
	c. Binopunctoure diversion.	(c)	」 ¹ /	k. Pioglitazone (Actos):	(1)
	d. Other GI or bariatric surgery (speci	fv): (.)	l. Repaglinide (Prandin):	(.)
			17	m. Rosiglitazone (Avandia):	(1)
	e. None of the above:		1)	n. Tolazamide (Tolinase):	(1/
	C. Mone of the above.	(1/	o. Tolbutamide (Orinase):	(1)
				p. Other, (specify):	(1/
				p. Onici, (specify).	(1/
				q. None of the above:	(

55.	Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 6 months (<i>check all that apply</i>):		
	a. Chlordiazepoxide (Librium):	(1)
	b. Clorazepate dipotassium (Tranxene):	(1)
	c. Diazepam (Valium):	(1)
	d. Disulfiram (Antabuse):	(1)
	e. Hydroxyzine pamoate (Vistaril):	(1)
	f. Naltrexone hydrochloride (Revia):	(1)
	g. Other, (specify):	(1)
	h. None of the above:	(1)
56.	Has the patient taken any antihyperlipidemic medications in the past 6 months (check all that apply):		
	a. Atorvastatin (Lipitor):	(1)
	b. Colestipol hydrochloride (Colestid):	(1)
	c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate):	(1)
	d. Gemfibrozil (Gen-Fibro, Lopid):	(1)
	e. Fenofibrate (Tricor):	(1)
	f. Fluvastatin sodium (Lescol):	(1)
	g. Lovastatin (Mevacor):	(1)
	h. Nicotinic acid (Niaspan):	(1)
	i. Pravastatin sodium (Pravachol):	(1)
	j. Rosuvastatin (Crestor):	(1)
	k. Simvastatin (Zocor):	(1)
	l. Other, (specify):	(1)
	m. None of the above:	(1)

57. Has the patient taken any antiobesity medications in the past 6 months (<i>check all that apply</i>):		
a. Dexfenfluramine hydrochloride (Redux):	(₁)
b. Fenfluramine hydrochloride (Pondimin):	(1)
c. Methamphetamine hydrochloride (Desoxyn, Gradumet):	(1)
d. Orlistat (Xenical):	(1)
e. Phendimetrazine tartrate (Adipost, Bontril):	(1)
f. Phentermine hydrochloride (Adipex, Fastin, Ionamin, Teramine):	(1)
g. Sibutramine hydrochloride monohydrate (Meridia):	(1)
h. Other, (specify):	(1)
i. Other, (specify):	(1)
j. None of the above:	(1)
58. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 6 months (<i>check all that apply</i>):		
a. Acetaminophen (Tylenol):	(1)
b. Aspirin - 325 mg:	(1)
c. Aspirin - 81 mg:	(1)
d. Celecoxib (Celebrex):	(1)
e. Ibuprofen (Advil, Motrin):	(1)
f. Indomethacin (Indocin):	(1)
g. Naproxen (Aleve, Naprosyn):	(1)
h. Rofecoxib (Vioxx):	(1)
i. Other, (specify):	(1)
j. Other, (specify):	(1)
k. Other, (specify):	(1)
l. None of the above:		

59.	Has the patient taken any strong opiates containing acetaminophen medication in the past 6 months (<i>check all that apply</i>)			61. Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months (<i>check all that apply</i>):
	a. Darvocet:	(1)	a. Clopidogrel (Plavix):
	b. Esgic - Plus:	(1)	b. Dipyridamole:
	c. Fioricet:	(1)	c. Heparin:
	d. Lorcet:	(1)	d. Ticlopide (Ticlid):
	e. Lortab:	(1)	e. Warfarin (Coumadin):
	f. Norco:	(1)	f. Other, (specify):
	g. Percocet:	(1)	
	h. Talacen:	(1)	g. Other, (specify):
	i. Tylenol #3:	(1)	
	j. Tylenol #4:	(1)	h. None of the above:
	k. Tylox:	(1)	
	1. Vicodin:	(1)	62. Has the patient taken any systemic corticosteroids in the past 6 months
	m. Wygesic:	(1)	(check all that apply):
	n. Other, (specify):	(1)	a. Betamethasone sodium (Celestone):
				b. Cortisol:
	o. None of the above:	(1)	c. Cortisone:
				d. Dexamethasone (Decadron):
60.	Has the patient taken any histamine H2 receptor antagonists/other gastrointestinal			e. Hydrocortisone (Hydrocortone):
	medications in the past 6 months (check all	!		f. Methylprednisolone (Solu-Medrol):
	hat apply):a. Cimetidine (Tagamet):	(1)	g. Prednisolone (Prelone):
	b. Esomeprazole magnesium (Nexium):	(1)	h. Prednisone:
	c. Famotidine (Pepcid):	(1)	i. Triamcinolone (Acetocot, Amcort,
	d. Lansoprazole (Prevacid):	(1)	Aristocort, Kenacort):
	e. Nizatidine (Axid):	(1)	j. Other, (specify):
	f. Omeprazole (Prilosec):	(1)	
	g. Ranitidine (Zantac):	(1)	k. Other, (specify):
	h. Ranitidine bismuth citrate (Tritec):	(1)	
	i. Antacids, (specify):	(1)	l. None of the above:
	1. Tinucius, (specify).	(1/	
	j. Other, (specify):	(1)	
	k. Other, (specify):	(1)	
	l. None of the above:	(1)	

Has the patient taken any cardiovascular or antihypertensive medications in the past 6 months (check all that apply):			64. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months (about all that are half).		
a. Amiodarone (Pacerone):	(1)	in the past 6 months (check all that apply):		
b. Amlodipine besylate (Norvasc):	(1)	a. Conjugated estrogen (Premarin/Prempro):	(1)
c. Atenolol (Tenormin):	(1)	b. Diethylstilbestrol and		1,
d. Benazepril (Lotensin):	(1)	methyltestosterone (Tylosterone):	(1)
e. Captopril (Capoten):	(1)	c. Esterified estrogen (Estratab, Menest):	(1)
f. Clonidine (Catapres):	(1)	d. Estradiol (Estrace):	(1)
g. Digoxin (Lanoxin):	(1)	e. Ethinyl estradiol (Estinyl):	(1)
h. Diltiazem (Cardizem):	(1)	f. Fluoxymesterone (Android-F,	,	,
i. Doxazosin (Cardura):	(1)	Halotestin):	(1)
j. Enalapril (Vasotec):	(1)	g. Levonorgestrel (Norplant):	(1)
k. Felodipine (Plendil):	(1)	h. Medroxyprogesterone (Cycrin, Provera):	(1)
l. Furosemide (Lasix):	(1)	i. Megestrol (Megace):	(1)
m. Hydrochlorothiazide (Esidrix, 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, Levlen, Levlite, Levora, Loestrin, 		
r. Metoprolol (Lopressor):	(1)	Lo-Ovral, Necon, Nelova, Nordette,		
s. Nifedipine (Adalat, Procardia):	(1)	Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen,		
t. Perhexiline maleate:	(1)	Ovral, Tri-Levlen, Triphasil, Trivora,	(`
u. Propranolol (Inderal):	(1)	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)

65.	Has the patient taken any allergy or asthma medications in the past 6 months			69. Has the patient taken any supplements in the past 6 months (<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):	(1)
	d. Fluticasone propionate (Flonase, Flovent):	(1)	f. Carnitine (any form):	(1)
	e. Loratadine (Claritin):	(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)
				k. Dichloroacetate:	(1)
	i. Other, (specify):	(1)	l. Echinacea:	(1)
		`	1/	m. Fish oil (any form):	(1)
	j. None of the above:	(1)	n. Flax seed oil:	(1)
	3	`	1/	o. Garlic:	(1)
66.	Has the patient taken a multivitamin regularly in the past 6 months:			p. Ginkgo biloba:	(1)
	Yes (1)	N	No 2)	q. Glucosamine (any form):	(1)
	(1)	(2)	r. Lecithin:	(1)
67.	Has the patient taken vitamins other than			s. Magnesium:	(1)
	multivitamins in the past 6 months:	(No		t. Milk thistle:	(1)
	(1)			u. N-acetyl-cysteine:	(1)
	69		_	v. Potassium (any form):	(1)
68.	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):	(1)
			 -	ad. Other, (specify):	(1)

ae. None of the above:

70.	. Has patient taken any of the following medications or other supplements/medications in the past 6 months (record all other supplements/medications):							
	a. Demeclocycline (Declomycin):	(1)					
	b. Divalproex (Depakote):							
	c. Doxycycline (Monodox):	(1)					
	d. Isotretinoin (Accutane):	(1)					
	e. Levothyroxine (Levoxyl, Synthroid):	(1)					
	f. Liothyronine (Cytomel):	(1)					
	g. Methotrexate (Rheumatrex):	(1)					
	h. Minocycline (Dynacin, Minocin):	(1)					
	i. Oxytetracycline (Terramycin):		1)					
	j. Penicillamine (Cuprimine, Depen):							
	k. Tetracycline (Achromycin):							
	l. Trientine hydrochloride (Syprine):							
	m. Ursodeoxycholic acid (Actigall, Urso, Ursodiol):							
	n. Valproate sodium (Depacon):							
	o. Valproic acid (Depakene):							
	<pre>p. Other, (specify): q. Other, (specify):</pre>							
	r. Other, (specify):							
	s. Other, (specify):	(1)					
	t. Other, (specify):	(1)					
	u. None of the above:	(1)					

71. Study Physician PIN:
72. Study Physician signature:
73. Clinical Coordinator PIN:
74. Clinical Coordinator signature:

I. Administrative information

75. Date form reviewed:		
	mon	year

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

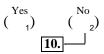
- **1.** Center ID: ____ ___ ___
- **2.** Patient ID: ____ __ ___
- 3. Patient code:
- **4.** Visit date (date this form is initiated):

_		_
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

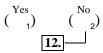
8. Do any of the patient's first degree relatives (parent, brother, sister, child) have liver disease:



- **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
----	-------	---------

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:

Y	es	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):

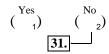
6. What is the most the patient has ever weighed:			
		lbs	

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	

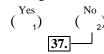
33. Does the patient weigh less than he/she did one year ago:



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:



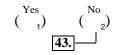
36. Which did the patient try to do (*check only one*):

Gain weight	(1)
Lose weight	(2)

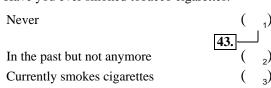
E. Tobacco cigarette smoking history

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

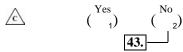
37. Is the patient age 8 or older:



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):

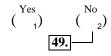
years

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

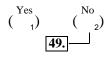
garettes/day
igai ettes/uay

F. Menstrual history

43. Is the patient female:



44. Has menarche occurred:



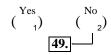
45. What was the patient's age at menarche:

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)
b. Has the patient ever received any			d. Disulfiram (Antabuse):	(1)
other organ, limb, or bone marrow transplant:			e. Hydroxyzine pamoate (Vistaril):	(1)
Yes	(N	No 2)	f. Naltrexone hydrochloride (Revia):	(1) 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	`	17	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):	(1)
d. Estradiol (Estrace):	(1)
e. Ethinyl estradiol (Estinyl):	(1)
f. Fluoxymesterone (Android-F, Halotestin):	(1)
g. Levonorgestrel (Norplant):	(1)
h. Medroxyprogesterone (Cycrin, Provera):	(1)
i. Megestrol (Megace):	(1)
j. Methyltestosterone (Android):	(1)
k. Nandrolone (Deca-Durabolin, Hybolin Decanoate, Kabolin):	(₁)
l. Norethindrone (Micronor):	(1)
m. Norgestrel (Ovrette):	(1)
n. Oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia):	(1)
o. Oxandrolone (Oxandrin):	(1)
p. Oxymetholone (Anadrol):	(1)
q. Progesterone (Prometrium):	(1)
r. Raloxifene (Evista):	(1)
s. Tamoxifen (Nolvadex):	(1)
t. Other, (specify):	(1)
u. Other, (specify):	(1)
v. None of the above:	(1)

65. Has the patient taken any allergy or asthma medications in the past 6 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) 1)	supplements/medications in the past 6 months (record all other
b. Alpha-tocopherol:	(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):h. Choline + methionine + betaine +	(1)	e. Levothyroxine (Levoxyl, Synthroid):
			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:	(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

year

NAFLD Database

BP - Blood Processing for Plasma and Serum

Purpose: Document collection of fasting blood for local separation of plasma and serum and shipment to NIDDK Biosample Repository at Fisher BioServices.

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

By whom: Clinical Coordinator and laboratory personnel responsible for collection and processing of whole blood. **Instructions**: Label CTAD and SST tubes of whole blood using labels specific for the patient and visit; these labels are generated by the clinic upon registration (screening labels) or after enrollment (followup visit labels). Attach duplicate whole blood tube labels in items 11 and 13. For plasma: Fill one 4.5 mL CTAD tube with whole blood. For serum: Fill four 10 mL SST red top tubes with whole blood. Process blood for plasma and serum within two hours. After separation, prepare 5 or 6 aliquots of plasma, depending on volume of plasma obtained: transfer 0.5 mL of plasma to each of 5 or 6 (2.0 mL) cryovials. After separation, prepare 40 aliquots of serum: transfer 0.5 mL of serum to each of 40 (2.0 mL) cryovials. Label aliquots with numbered patient-specific plasma (blue top) and serum (red top) cryovial labels provided by the DCC. Choose one of the cryovial label sets provided by the DCC for this patient for use with this visit. Affix serum aliquot #00 label and plasma aliquot #00 label to this form in item 18. The LS code (or Vcode if using old labels) keyed from the labels in item 18 of this form links the cryovials collected today with the date and visit identified in items 4 and 5 of this form. Freeze labeled aliquots of plasma and serum immediately according to procedures specified in the NAFLD Database SOP, Part I. NOTE: Immediately upon completion of plasma and serum aliquot preparation, destroy any leftover cryovial labels from the label set used at this visit; use of these cryovial labels at any other visit will result in aliquots from both visits being unusable since the visit at which they were collected will not be able to be deter-

A. Center, patient and visit identification	9. Date and tim	e of blood dr	aw
1. Center code:	a. Date:		
		day	mon
2. Patient ID:	b. Time:		(
3. Patient code:	hour	minute	an
3. Patient code:	10. Number of C	CTAD (blue-to	op) tubes:
4. Date of visit:			
	11. Attach duplie	cate CTAD tu	ibe label:
day mon year			
5. Visit code:	NAFLD DB	Form, BP Pl	
5. Visit code.	Pt: 9	999, xyz	
6. Form & revision:bp1	Visit v	VVVV	
NATI D Detakes 1	Date:		
7. Study: NAFLD Database 1			
B. Processing whole blood Plasma and serum aliquots are to be separated from whole blood per instructions in the SOP. Draw fasting blood in the morning.			
8. Was blood collected for the NIDDK Biosample Repository:			
Yes (1)			
No, patient was not fasting for 12 hours (2)			
No, other reason (specify):			

specify other reason

Patient ID:	

12. Number of SST serum (red-top) tubes:	separator tubes	18. Attach duplicate cryovial labels (use aliquot #00 labels which are located in first row of labels in the set):	
13. Attach duplicate SST s tube labels:	serum separator	Serum aliquot #00 label	Plasma aliquot #00 label
NAFLD DB Serum 1	NAFLD DB Serum 2		
Pt: 9999, xyz	Pt: 9999, xyz		
Visit: vvvv	Visit: vvvv		
BP	BP		
Date:	Date:		
L	1		
NAFLD DB Serum 3	NAFLD DB Serum 4		
Pt: 9999, xyz	Pt: 9999, xyz	10 T. 1	
Visit: vvvv	Visit: vvvv	19. Technician:	
BP	BP		
Date:	Date:		print name
		D. Freezing aliquots	
			d serum aliquots immediately at
14. Phlebotomist:		-70°C or -20°C.	If frozen at -20°C, the cryovials
			red to -70°C within 24 hours. ly to the NIDDK BioSample Re-
p	orint name	pository at Fisher	
C. Aliquots for plasma and	d carum	20 Data and time amount	
	na into each of up to six 2.0	20. Date and time cryo or -20°C	oviais frozen in -/0°C
	als and pour 0.5 mL of		
serum into each of fort cryovials.	ty 2.0 mL pre-labeled	a. Date:	
15. Date and time of separ	ation into plasma	b. Time:	•
and serum aliquots	1	::	(1) (2)
a. Date:		hour n	ninute am pm
=		21. Number of cryovia	als frozen:
b. Time:	mon year	,	
D. 11111e. :	(1) (2)	22. Technician:	
hour minute		 v 100	
16. Number of aliquots for	plasma:		print name
		E. Administrative info	ormation
17. Number of aliquots for	serum:	E. Administrative into	mation
		23. Clinical Coordinat	tor PIN:
		24. Clinical Coordinat	tor signature:
		25. Date form reviewe	ed:
		day	mon year

CG - Genetic Consent Documentation

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

When: Visit s2 and as needed during followup (during followup, use the visit code of the followup visit that is open).

By whom: Study Physician and Clinical Coordinator.

Instructions: Complete this form based on the consent documents signed by the patient/parent. If the patient changes his/her mind regarding consent for use of samples after the initial form is completed, complete a new CG form.

A. Center, patient and visit identification	11. Other information related to consent for genetic research that clinic staff feel
1. Center ID:	needs to be keyed to the study database (e.g., if your genetic consent had other options that are not covered by the 3 categories of use of samples
2. Patient ID:	specified above):
3. Patient code:	
4. Date form completed:	
day mon year	
5. Visit code:	,
6. Form & revision:cg1	12. In your judgment, has the patient/parent consented to collection of blood for DNA banking (this question is asked in recognition that
7. Study: NAFLD Database 1	not all IRBs will have approved consent statements that include language that can be mapped into the questions in items 8 through 10; a response of "No" to this question (item 12) means that blood
B. Consent for collection, storage, and use of blood samples for current and future genetic research	should <u>NOT</u> be collected for sending to the Genetics Repository and if already collected, should be destroyed by the Genetics Repository):
8. Does the patient/parent consent to genetic research on NAFLD or	$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$
cryptogenic cirrhosis that is currently planned by the study investigators:	C. Administrative information
	13. Study Physician PIN:
9. Does the patient/parent consent to future genetic research on NAFLD or	14. Study Physician signature:
cryptogenic cirrhosis by this study or other study investigators:	
$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$	15. Clinical Coordinator PIN:
	16. Clinical Coordinator signature:
10. Does the patient/parent consent to future genetic research not related to NAFLD or	
cryptogenic cirrhosis by this study or other study investigators:	17. Date form reviewed:
$ \begin{pmatrix} Yes & No \\ & 1 \end{pmatrix} $	day mon year
\ 11 \ 21	day mon year

CR - 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. Biopsy slides may have visit code s1, f024, f048, f096, f144, or f192. During followup, specify the visit code for the followup visit that is currently open (check the patient's visit time window guide).

By whom: Data Coordinating Center staff member.

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 Data Coordinating Center personnel.

A. Center, participant and	d visit ident	tification		11. Steatosis (assume macro, e.g., large and droplet)	nd sn	nall
1. Center ID:				a. Grade:		
				< 5%	(0
2. Patient ID:				5-33%	(1)
				34-66%	(2)
3. Patient code:	_			> 66%	(3)
				b. Location:	`	3/
4. Date of biopsy:				Zone 3	(0
				Zone 1	(1)
	mon	vear		Azonal	(2)
,		<i>J</i>		Panacinar	(3)
5. Visit code:				c. Microvesicular steatosis, contiguous patches:		
6. Form & revision:	_	<u>c r </u>	1	Not present	(0
				Present	(1)
7. Study:	NAFLD	Database_	1_	12. Fibrosis stage (Masson's trichrome stain))	
B. Central reading				0: None	(0
8. Date of central reading	g:			1a: Mild, zone 3, perisinusoidal (requires trichome)	(1)
		 		1b: Moderate, zone 3, perisinusoidal (easily seen on H&E)	(2)
day	mon	year		1c: Portal/periportal only	(3)
9. Which stained slides a review (<i>check all that</i>		for		2: Zone 3 and periportal, any combination	(4)
a. H & E:		(1)	3: Bridging	(5)
b. Masson's trichome		(1)	4: Cirrhosis	(6)
	•	(
c. Iron:		(1)			
d. Other (specify):		(1)			
10. Biopsy length:						
1 2 6		mm	_			

13. Inflammation	17. Iron st	ain
a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci: 0 < 2 under 20x mag 2-4 under 20x mag > 4 under 20x mag b. Microgranulomas seen: (Yes (1) c. Large lipogranulomas seen: (Yes (1) d. Amount of portal, chronic inflammation: 0: None 1a: Mild 1b: More than mild 14. Liver cell injury a. Ballooning: None Few Many b. Acidophil bodies: Rare Many c. Pigmented macrophages: Rare/absent	a. Hep Ab Bar O) Dis 1) Dis 2) Ma 3) b. Hep Per Par No 2) C. Sin No Mi Mc d. Sin Por 1) 18. Is this No Suspic Yes, C O) 19. Is cirrl	patocellular grade: sent or barely discernible, 40x rely discernible granules, 20x rely discernible, 20x rely discernible granules, 20x rely discernible gr
Many d. Megamitochondria: Rare/absent Many	0)	(Yes (No 2) 21. ——) committee's opinion, is this
15. Mallory bodies Rare/absent Many 16. Glycogen nuclei: Rare/absent Many	crypto fails to withou	ogenic cirrhosis (cirrhosis that o meet criteria for NAFLD and ut evidence of other form(s) of ic liver disease): Yes No ()

21. Other fe	eatures (check all that apply)		
a. Mall	lory's hyaline (r/o cholate stasi	s): (1/
b. Peris	sinusoidal fibrosis away from a:	(\ 1⁄
c. Hepa	atocyte ballooning:	(1/
d. Meg	gamitochondria:	(1/
e. Othe	er (specify):	(1/
f. None	e:	(1/
22. Other c	omments (specify):		
C. Administ	trative information		
23. Data Co	oordinating Center personnel re:		
24. Date for	rm reviewed:		
	day mon	year	

ED - Database Enrollment

Purpose: • Check eligibility for NAFLD Database.

• Record reasons for ineligibility for patients found to be ineligible.

When: Visit s2.

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

Respondent: Patient and Clinical Coordinator.

Instructions: If is checked for any item, complete the entire form but note that the patient may not continue in the NAFLD Database. If an item has not been assessed because the patient is ineligible, write "m" (missing) next to that item. This form should be keyed for each patient for whom Form RG was completed without encountering a condition.

A. Center, patien	t, and visit	identification
-------------------	--------------	----------------

- **2.** Patient ID: ____ ___ ____
- **3.** Patient code:
- and/or Clinical Coordinator, is the patient's alcohol use since starting the screening process consistent with NAFLD:

9. In the judgment of the Study Physician



- **4.** Visit date (date this form is initiated):
 - day mon year
- **5.** Visit code: <u>s 2 _____</u> ____
- **6.** Form & revision: <u>e d 1</u>
- 7. Study: NAFLD Database 1

B. Alcohol use history consistent with NAFLD

8. On average, how many drinks containing alcohol has the patient had per week in the 2 years prior to screening:

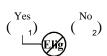
Less than one drink a week	(1
One drink a week	(2
2 to 4 drinks a week	(3
5 to 7 drinks a week	(4
8 to 10 drinks a week	(* 5
11 to 14 drinks a week	(* 6
15 or more drinks a week	(,7
	(Exig)—

C. Exclusions

- **10.** Do any of the patient's assessments show evidence of these medical exclusions
 - **a.** Total parenteral nutrition (TPN) within 3 months prior to screening:



b. Short bowel syndrome:



c. History of gastric or jejunoileal bypass prior to the diagnosis of NAFLD (bariatric surgery performed concomitant with or following the diagnosis of NAFLD is not exclusionary):



d. History of biliopancreatic diversion:



^{*} Patient is ineligible if female

- 11. Child-Pugh Turcotte score
 - **a.** Serum albumin subscore (from Form LR: > 3.5 g/dL = 1, 2.8-3.5 = 2, < 2.8=3):
 - **b.** Serum total bilirubin subscore (from Form LR: < 2.0 mg/dL=1, 2.0-3.0=2, > 3.0=3):
 - **c.** INR subscore (from Form LR: < 1.7=1, 1.7-2.3=2, > 2.3=3):
 - **d.** Ascites subscore (use all available information from all sources to score; None=1, Mild, easily managed=2, Severe, refractory=3):
 - e. Hepatic encephalopathy subscore (use all available information from all sources to score; None=1, Mild, easily managed=2, Severe, refractory=3):

 - **g.** Evidence of advanced liver disease (*Child-Pugh-Turcotte score at least 10*):

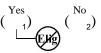


1-3

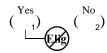
1-3

1-3

- **12.** Do any of the patient's assessments show evidence of these medical exclusions
 - **a.** Evidence of chronic hepatitis B as marked by the presence of HBsAg in serum (patients with isolated anti-HBc are not excluded):



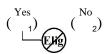
b. Evidence of chronic hepatitis C as marked by the presence of anti-HCV or HCV RNA in serum:



c. Low alpha-1-antitrypsin level and ZZ phenotype (*physician judgment*):



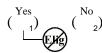
d. Wilson's disease:



e. Known glycogen storage disease:



f. Known dysbetalipoproteinemia:



g. Known phenotypic hemochromatosis (removal of > 4 g of iron by phlebotomy in an individual 18 or older):



h. Congenital hepatic fibrosis, polycystic liver disease:



i. Other metabolic/congenital liver disease:



j. HIV infection or other systemic infectious disease:



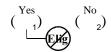
k. Disseminated or advanced extrahepatic malignancy:



l. Other severe systemic illness that in the opinion of the investigator would interfere with completion of followup:



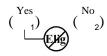
- **13.** Do any of the patient's assessments show evidence of these histologic exclusions
 - **a.** Hepatic iron index > 1.9:



b. Prominent bile duct injury (*florid duct lesions or periductal sclerosis*) or bile duct paucity:



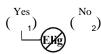
c. Chronic cholestasis:



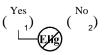
d. Vascular lesions (vasculitis, cardiac sclerosis, acute or chronic Budd-Chiari, hepatoportal sclerosis, peliosis):



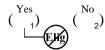
e. Iron overload greater than 3+:



f. Zones of confluent necrosis, infarction, massive or sub-massive, pan-acinar necrosis:



g. Multiple epithelioid granulomas:



14. Is there any other condition or issue that, in the opinion of the investigator, would interfere with the patient's adherence to study requirements:



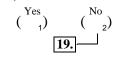
- D. Check on imaging and histologic criteria for inclusion in Database
- **15.** Does the patient have at least 5% steatosis on biopsy:

Yes	(1)
No	(2)
No biopsy available	(3)

16. Does the patient have cryptogenic cirrhosis on biopsy (*cirrhosis but with less than 5% steatosis*):

Yes	(1)
No	(2)
No biopsy available	(2)

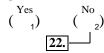
17. Does the patient have an imaging study obtained in the past year that is suggestive of NAFLD (*physician judgment*, *criteria not specified*):



18. Imaging studies suggestive of NAFLD (*check all that apply*)

a. Upper abdominal ultrasound:	(1)
b. Upper abdominal CT scan:	(1)
c. Upper abdominal MRI:	(1)

19. Does the patient have an imaging study compatible with cirrhosis (*small liver*, *nodularity*, *heterogeneous echo pattern*):



1)

20. Imaging studies suggestive of cirrhosis (*check all that apply*)

a. Upper abdominal ultrasound: (1)
---	----

- **b.** Upper abdominal CT scan: (1)
- **c.** Upper abdominal MRI: (1)
- **21.** Does the patient have any of the following findings
 - a. Imaging evidence of portal hypertension (splenomegaly, portosystemic collaterals): (
 - **b.** Albumin less than 3.5 g/dL:
 - **c.** INR greater than 1.3:
 - **d.** Platelet count less than 140,000 cells/uL:
 - e. Esophageal or gastric varices on endoscopy: (,
 - **f.** Ascites on physical exam or imaging study: (,)
 - **g.** None of the above: $\binom{1}{1}$

E. Diagnostic category for inclusion

22. Diagnostic category for inclusion *(check only one):*

Definite NAFLD (*item 15 = Yes*) $\binom{1}{2}$

Definite cryptogenic cirrhosis (item 16 = Yes)

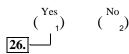
Suspected NAFLD (item 17 = Yes and at least one of items 18a-c is checked) (3)

Suspected (clinical) cryptogenic cirrhosis (item 19 = Yes and at least one of items 20a-c is checked and at least one of items 21a-f is checked)

None of the above

F. Eligibility check

23. Was an ineligibility condition checked 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:

Yes

No

Task not run because patient is known to be ineligible

(* 3)

*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):

Patient ID:	 	

H. Administrative information

day

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

mon

year

ED - Database Enrollment

Purpose: • Check eligibility for NAFLD Database.

• Record reasons for ineligibility for patients found to be ineligible.

When: Visit s2.

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

<u>e</u> <u>d</u> 2

NAFLD Database 1

Respondent: Patient and Clinical Coordinator.

Instructions: If is checked for any item, complete the entire form but note that the patient may not continue in the NAFLD Database. If an item has not been assessed because the patient is ineligible, write "m" (missing) next to that item. This form should be keyed for each patient for whom Form RG was completed without encountering a or condition.

A. Center, patient	t, and visit ic	lentif	ication		
1. Center ID:					
2. Patient ID:					
3. Patient code:					
4. Visit date (da.	te this form i	s initi	ated):		
d	ay	mon		yea	ır
5. Visit code:		_S	_2		

B. Alcohol use history consistent with NAFLD

6. Form & revision:

7. Study:

8. On average, how many drinks containing alcohol has the patient had per week in the 2 years prior to screening:

Less than one drink a week	(1)
One drink a week	(2)
2 to 4 drinks a week	(3)
5 to 7 drinks a week	(4)
8 to 10 drinks a week	(* 5)
11 to 14 drinks a week	(* 6)
15 or more drinks a week	
	(Eleg)—

9. In the judgment of the Study Physician and/or Clinical Coordinator, is the patient's alcohol use since starting the screening process consistent with NAFLD:

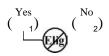


C. Exclusions

- **10.** Do any of the patient's assessments show evidence of these medical exclusions
 - **a.** Total parenteral nutrition (TPN) within 3 months prior to screening:



b. Short bowel syndrome:



c. History of gastric or jejunoileal bypass prior to the diagnosis of NAFLD (bariatric surgery performed concomitant with or following the diagnosis of NAFLD is not exclusionary):



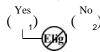
d. History of biliopancreatic diversion:



^{*} Patient is ineligible if female

- 11. Child-Pugh Turcotte score
 - **a.** Serum albumin subscore (from Form LR: > 3.5 g/dL=1, 2.8-3.5=2, < 2.8=3): $\frac{1}{1-3}$
 - **b.** Serum total bilirubin subscore (from Form LR: < 2.0 mg/dL=1, 2.0-3.0=2, > 3.0=3):
 - **c.** INR subscore (from Form LR: < 1.7=1, 1.7-2.3=2, > 2.3=3):
 - **d.** Ascites subscore (use all available information from all sources to score; None=1, Mild, easily managed=2, Severe, refractory=3):
 - e. Hepatic encephalopathy subscore
 (use all available information from
 all sources to score; None=1,
 Mild, easily managed=2,
 Severe, refractory=3):

 - **g.** Evidence of advanced liver disease (*Child-Pugh-Turcotte score at least 10*):

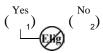


1-3

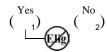
1-3

1-3

- **12.** Do any of the patient's assessments show evidence of these medical exclusions
 - **a.** Evidence of chronic hepatitis B as marked by the presence of HBsAg in serum (patients with isolated anti-HBc are not excluded):



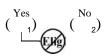
b. Evidence of chronic hepatitis C as marked by the presence of anti-HCV or HCV RNA in serum:



c. Low alpha-1-antitrypsin level and ZZ phenotype (*physician judgment*):



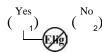
d. Wilson's disease:



e. Known glycogen storage disease:



f. Known dysbetalipoproteinemia:



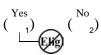
g. Known phenotypic hemochromatosis (removal of > 4 g of iron by phlebotomy in an individual 18 or older):



h. Congenital hepatic fibrosis, polycystic liver disease:



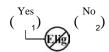
i. Other metabolic/congenital liver disease:



j. HIV infection or other systemic infectious disease:



k. Disseminated or advanced extrahepatic malignancy:



l. Other severe systemic illness that in the opinion of the investigator would interfere with completion of followup:



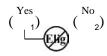
- **13.** Do any of the patient's assessments show evidence of these histologic exclusions
 - **a.** Hepatic iron index > 1.9:



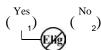
b. Prominent bile duct injury (*florid duct lesions or periductal sclerosis*) or bile duct paucity:



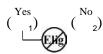
c. Chronic cholestasis:



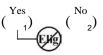
d. Vascular lesions (vasculitis, cardiac sclerosis, acute or chronic Budd-Chiari, hepatoportal sclerosis, peliosis):



e. Iron overload greater than 3+:



f. Zones of confluent necrosis, infarction, massive or sub-massive, pan-acinar necrosis:



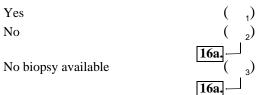
g. Multiple epithelioid granulomas:



14. Is there any other condition or issue that, in the opinion of the investigator, would interfere with the patient's adherence to study requirements:



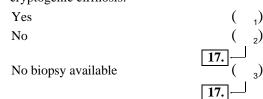
- D. Check on imaging and histologic criteria for inclusion in Database
- 15. 5% steatosis on biopsy
 - **a.** Did at least one biopsy show at least 5% steatosis:



b. Date of most recent biopsy showing at least 5% steatosis:



- **16.** Cryptogenic cirrhosis on biopsy
 - **a.** Did at least one biopsy show cryptogenic cirrhosis:



b. Date of most recent biopsy showing cryptogenic cirrhosis:

=		_
day	mon	year

17. Does the patient have an imaging study obtained in the past year that is suggestive of NAFLD (physician judgment, criteria not specified):

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	19.

- 18. Imaging studies suggestive of NAFLD (check all that apply)
 - 1) **a.** Upper abdominal ultrasound:
 - 1) **b.** Upper abdominal CT scan:
 - c. Upper abdominal MRI:
- 19. Does the patient have an imaging study obtained in the past year compatible with cirrhosis (small liver, nodularity, *heterogeneous echo pattern):*

Y	'es	N	lо
(1)	(2)
	2	2. —]

- 20. Imaging studies suggestive of cirrhosis (check all that apply)
 - **a.** Upper abdominal ultrasound:
 - 1) **b.** Upper abdominal CT scan:
 - **c.** Upper abdominal MRI:
- 21. Does the patient have any of the following findings
 - **a.** Imaging evidence of portal hypertension (splenomegaly, portosystemic collaterals): 1)
 - **b.** Albumin less than 3.5 g/dL:
 - **c.** INR greater than 1.3:
 - **d.** Platelet count less than 140,000 cells/uL:
 - e. Esophageal or gastric varices on endoscopy:
 - **f.** Ascites on physical exam or imaging study:
 - **g.** None of the above:

E. Diagnostic category for inclusion

22. Diagnostic category for inclusion (check only one):

> Definite NAFLD on most recent biopsy (item 15a = Yes and date in item 15b is *most recent biopsy date)*

1)

Definite NAFLD on biopsy in the past but not on a subsequent biopsy (item 15a = Yes and date in item 15b is not the most recent biopsy date)

Definite cryptogenic cirrhosis on most recent biopsy (item 16a = Yes and date in item 16b is most recent biopsy date)

Suspected NAFLD (item 17 = Yes and at least one of items 18a-c is checked)

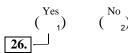
Suspected (clinical) cryptogenic cirrhosis (item 19 = Yes and at least one of items 20a-c is checked and at least one of items 21a-f is checked)

None of the above



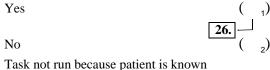
F. Eligibility check

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.

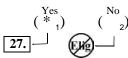
24. Were any STOP's or ineligible conditions other than "missing Form ED" identified by the Enrollment Task:



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

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:
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:	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:	23. Date of blood draw for HbA1c:
11. White blood cell count (WBC):	day mon year
$\frac{10^3 \text{ cells/}\mu\text{L or } 10^9 \text{ cells/}\text{L}}{10^9 \text{ cells/}\text{L}}$	Date must be within the required time window: within 3 months of screening or in the time window for the followup visit (check the patient's Database
12. Platelet count:	visit time window guide).

cells/ μL

% rotein	day mo	n year
	Date must be within the req within 6 months of screening o	uired time window. or in the time window
panel:	for the followup visit (check th visit time window guide).	
quired time window: or in the time window	37. Alpha feto protein:	
	E. Fasting lipid profile	
•	Fasting is defined as nothing	ng by mouth except
mg/dL	water for greater than or equ to blood draw.	tal to 12 hours prior
mg/dL	38. Date of blood draw for fasting profile:	g lipid
AST)	·	n year
	Date must be within the req within 6 months of screening o	nuired time window. or in the time window
U/L		e patient's Database
	a. Triglycerides:	
I T)		mg/uL
LI)	b. Total cholesterol:	
		mg/dL
	c. HDL cholesterol:	
U/L		mg/dL
	d LDL cholesterol:	
U/L	u. EDE cholesterol.	mg/dL
U/L		
U/L	water for greater than or equ to blood draw.	ai io 12 nours prioi
O/L	39. Date of blood draw for fasting	g glucose
(GGT):	and insulin levels:	
		n year
U/L	,	,
•	within 6 months of screening o	or in the time window
g/dL	for the followup visit (check th visit time window guide).	e patient's Database
•	a. Serum glucose:	
g/dL		mg/dL
	b. Serum insulin:	
_		
	quired time window: or in the time window he patient's Database mg/dL mg/dL AST) U/L U/L U/L U/L U/L U/L U/L U/	visit time window guide). 7. Alpha feto protein: 7. Alpha feto protein: 7. Alpha feto protein: 7. Alpha feto protein: 8. Fasting lipid profile 8. Fasting is defined as nothing water for greater than or equate to blood draw. 8. Date of blood draw for fasting profile: 8. AST) 8. Date of blood draw for fasting profile: 8. Date must be within the requition of months of screening of for the followup visit (check the visit time window guide). 8. Triglycerides: 8. Date of blood draw for fasting profile: 8. Triglycerides: 8. Date must be within the requition of months of screening of for the followup visit (check the visit time window guide). 9. Total cholesterol: 10/L 10/

Patient ID:		

G. Administrative information

40. Study Physician PIN:

41. Study Physician signature:

42. Clinical Coordinator PIN:

43. Clinical Coordinator signature:

44. Date form reviewed:

day mon year

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 10^3 cells/ μ 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 value. ues 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 for the followup visit (check the patient's Database		
3. Patient code:	visit time window guide).		
4. Date of visit (date form was initiated):	14. Sodium:		
day mon year	15. Potassium:		
5. Visit code:	mEq/L		
6. Form & revision:1 r2	16. Chloride:		
7. Study: NAFLD Database 1	17. Bicarbonate:		
B. Hematology	18. Calcium:		
8. Date of blood draw for complete blood count:	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:	23. Date of blood draw for HbA1c:		
11. White blood cell count (WBC):	day mon year		
$\frac{\bullet}{10^3 \text{ cells/}\mu\text{L or } 10^9 \text{ cells/}\text{L}}$	Date must be within the required time window: within 3 months of screening or in the time window for the followup visit (check the patient's Database		
12. Platelet count:	visit time window guide).		

cells/ μL

		Patient ID:
24. HbA1c:		36. Date of blood draw for alpha feto protein:
D. Liver panel and alpha feto 25. Date of blood draw for live		day mon year Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).
day Date must be within the within 6 months of screening for the followup visit (check visit time window guide).	ng or in the time window	37. Alpha feto protein:
		E. Fasting lipid profile
26. Bilirubin (total):		Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior to blood draw.
27. Bilirubin (direct):	mg/dL	38. Date of blood draw for fasting lipid profile:
28. Aspartate aminotransferase	e (AST)	day mon year
a. Upper limit of normal:	U/L	Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database visit time window guide).
b. Lower limit of normal:		a. Triglycerides: mg/dL
29. Alanine aminotransferase	·	b. Total cholesterol: mg/dL
a. Upper limit of normal:	U/L	c. HDL cholesterol: mg/dL
b. Lower limit of normal:		d. LDL cholesterol: mg/dL
30. Alkaline phosphatase		F. Fasting glucose and insulin
a. Upper limit of normal:		Fasting is defined as nothing by mouth except water for greater than or equal to 12 hours prior
b. Lower limit of normal:		to blood draw.
31. Gamma glutamyl transfera	ase (GGT):	39. Date of blood draw for fasting glucose and insulin levels:
32. Total protein:		day mon year Date must be within the required time window: within 6 months of screening or in the time window for the followup visit (check the patient's Database
22 411 :	g/dL	visit time window guide). a. Serum glucose:
33. Albumin:	g/dL	b. Serum insulin:

34. Prothrombin time (PT):

35. International normalized ratio (INR):

 $\mu u/mL$

Patient ID:	 	

	G.	Admir	istrative	inform	ation
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40. Study Physician PIN:

41. Study Physician signature:

42. Clinical Coordinator PIN: ____ ____

43. Clinical Coordinator signature:

44. Date form reviewed:

day mon year

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:			
$\frac{\bullet}{10^3 \text{ cells/}\mu\text{L or } 10^9 \text{ cells/}L}$	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	na 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	iistra	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.

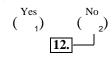
When: Visit s1.

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:

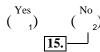


11. Hepatic iron index:

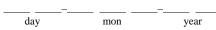
•	
μMo1/g/year	

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:

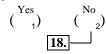


14. Type of abnormality (*WT* = *wild type*; *check only one*):

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:

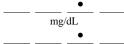


16. Date of blood draw for ceruloplasmin: (required only if patient is 40 years old or younger):



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.

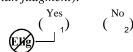
- **19.** Alpha-1 antitrypsin (A1AT)
 - **a.** Upper limit of normal: $\underline{\hspace{1cm}}_{mg/dL} \underline{\hspace{1cm}}_{mg/dL}$
 - **b.** Lower limit of normal: _____ mg/dL
- **20.** A1AT phenotype (*if unknown record as "m"*)
 - **a.** Pi Z heterozygote:

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

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.

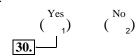
25. Antimitochondrial antibody (AMA)*:

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)*:

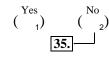
Positive (1)
Negative (2)

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:

LT - Liver Tissue Banking

Purpose: To document collection of extra liver tissue and flash freeze procedures for liver specimen banking. **When**: Whenever more than 2 cm of liver tissue are obtained during a biopsy. If you have more than one pre-enrollment biopsy with flash frozen liver tissue available, contact the Data Coordinating Center. Only one LT form may be completed prior to enrollment in the Database. Use visit code s1, f024, f048, f096, f144, f192, or in followup, use the code for the followup visit that is currently open (check the patient's visit time window guide). If after enrollment and before the f024 window is open, use visit code "n". This form is expected whenever the Liver Biopsy Materials Documentation (SD) form says liver tissue was obtained for banking.

By whom: Clinical Coordinator.

Instructions: Liver biopsy tissue should be obtained by a needle core biopsy (as opposed to a wedge biopsy) using a 16 or greater gauge needle. Whenever more than 2 cm of tissue are obtained during biopsy, place a 1-2 mm segment of liver tissue into a 2.0 mL polypropylene cryovial with preprinted label attached. Flash freeze liver tissue immediately (within 5 minutes following biopsy) by placing labeled cryovial containing liver tissue into a portable liquid nitrogen container. Store the cyrovial locally in -70° C (or colder) freezer temporarily and batch ship cryovials on dry ice monthly to the NIDDK Biosample Repository located at McKesson Bioservices.

A. Center, patient and visit identification		11. Was the liver tissue obtained from a needle core biopsy (as opposed to a wedge bi-
1. Center code:		opsy): $ {\operatorname{Yes} \atop {1 \choose 1}} {\operatorname{No} \atop {2}} $
2. Patient ID:		C. Cryovial label
3. Patient code:		12. Attach duplicate cryovial label:
4. Date form initiated:		
day mon	year	
5. Visit code (s1, n, or code for followup visit that is o	ppen):	
6. Form & revision:	1_	
7. Study: NAFLD Databa	ise_1_	
B. Liver biopsy		D. Flash freeze procedures
8. Date of biopsy:		13. Was tissue flash frozen within 5 minutes of biopsy by placing in portable liquid nitrogen container:
day mon	year	
9. Was the liver tissue obtained using a 16-gauge or greater needle:		15.
Yes (1)	$\binom{No}{2}$	14. Explain what was done and why protocol was not followed:
10. Was liver tissue obtained via a second		
pass: $\binom{\text{Yes}}{1}$	$\binom{No}{2}$	

Patient ID:	 	

15. Was tissue shipped on dry ice to the Biosample Repository on same day as biopsy:

16. Describe conditions of local storage prior to shipment to the Biosample Repository (e.g., temperature, date and time placed in freezer):

-		
-		
-		

E. Administrative information

- 17. Clinical Coordinator PIN:
- **18.** Clinical Coordinator signature:
- **19.** Date form reviewed: day mon year

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. Measure the hips at the fullest part.

A. Center, patient, and visit identification	10. Waist (standing, at midpoint between highest point of iliac crest and lowest part of costal margin)		
1. Center ID:	a. Circumference, 1st measurement:		
2. Patient ID:	waist circumference		
	b. Circumference, 2nd measurement:		
3. Patient code:	· · · · · · · · ·		
4.37.7.1	waist circumference		
4. Visit date:	c. Units:		
day mon year	Inches (1)		
	Centimeters (₂)		
5. Visit code:	11. Hip (standing, at fullest part of the hips)		
6. Form & revision:pe1	a. Circumference, 1st measurement:		
	<u> </u>		
7. Study: NAFLD Database 1	hip circumference		
	b. Circumference, 2nd measurement:		
B. Measurements	<u> </u>		
0 Haisht (-1	hip circumference c. Units:		
8. Height (shoes off)	Inches (,)		
a. 1st measurement:	Centimeters (2)		
b. 2nd measurement:	12. Temperature		
<u> </u>	(Oral or other, as appropriate for age)		
c. Units:			
Inches (1)	a. Degrees:		
Centimeters (₂)	b. Scale:		
9. Weight (shoes off)	Fahrenheit (4)		
	Centigrade (2)		
a. Weight, 1st measurement:			
<u> </u>	13. Blood pressure		
b. Weight, 2nd measurement:	a Systalia:		
<u> •</u>	a. Systolic: mmHg		
c. Units:	b. Diastolic:		
Pounds (1)	mmHg		
Kilograms (2)			

14. Resting radial pulse:		21. Neck:	
	beats/minute	Normal	(1)
15. Respiratory rate:	breaths/minute	Abnormal	22. (₂)
C. Examination findings		20.1	
16 Chin.		specify abnormality	
16. Skin:	()	22. Lymphatic:	
Normal	(1)	Normal	(1)
Abnormal	(₂)	Abnormal	23.
17. Acanthosis nigricans (check only	v one):	Abiloffilai	(2)
Absent (not detectable on close	inspection) $\begin{pmatrix} 0 \end{pmatrix}$	specify abnormality	
Present (clearly present on close		23. Chest and lungs:	
inspection, not visible to casual extent not measurable)	observer, $\begin{pmatrix} 1 \end{pmatrix}$	Normal	(1)
Mild (limited to base of skull, no extending to lateral margins of r < 3 inches in breadth)		Abnormal	25. (₂)
Moderate (extending to lateral not neck, 3-6 inches in breadth, n	nargins	24. Abnormality of the chest and lungs <i>(check all that apply)</i>	
from patient's front)	(3)	a. Hepatopulmonary syndrome:	(1)
Severe (extending anteriorly, > breadth, visible from front)	6 inches in (4)	b. Other (specify):	(1)
18. Other skin abnormality <i>(check a)</i>	ll that apply)	specify	
a. Jaundice:	(₁)	25. Heart:	
b. Palmar erythema:	$\begin{pmatrix} 1 \\ 1 \end{pmatrix}$	Normal	(,)
c. Spider angiomata:	$\begin{pmatrix} 1 \\ 1 \end{pmatrix}$		26.
d. Other (specify):	$\begin{pmatrix} 1 \\ 1 \end{pmatrix}$	Abnormal	(2)
		specify abnormality	
e. None of the above:	(1)	26. Abdomen:	
19. Head, eyes, ears, nose, throat:		Normal	(,)
Normal	(1)		28.
Ahnamal	21.	Abnormal	(2)
Abnormal	(₂)	27. Abdomen abnormality (check all that apply)	
20. Abnormality of the head, eyes, n throat	iose,	a. Ascites:	()
throat (check all that apply)			(1)
a. Jaundice:	(1)	b. Portal hypertension:	(1)
b. Other (specify):	(1)	c. Other (specify):	(1)
specify		specify	

28.	Liver	and	sp	leen:
20.	LIVUI	and	Sp.	LCCII.

Normal	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$
.,	30.
Abnormal	(₂)

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

	•	
	cm	
		1

- **b.** Hepatic encephalopathy: (1)
- **c.** Hepatocellular carcinoma: (1)
- **d.** Hepatopulmonary syndrome: (1)
- e. Hepatorenal syndrome:
- **f.** Splenomegaly: (1)
- g. Other (specify):

specify	

30. Extremities:

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

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

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

specify

32. Genitourinary/pelvis:

Not performed	()
Normal	34.
Abnormal	34.

33. Abnormality of the genitourinary/pelvis *(check all that apply):*

a. Hepatorenal syndrome: **b.** Other (specify):

specify	

34. Nervous system:

Not performed	(0
Normal	36. (₁)
Abnormal	36. (₂)

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

a. Hepatic encephalopathy: (1) **b.** Other (specify): (1)

D. Tanner Staging

36. Is Tanner staging required for this participant *(check only one):*

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

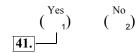
No, participant is 18 years old or older

45.

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

(₃)

37. Is the patient female:



Male Tanner Staging

38. Genital stage:

1-5

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



40. Pubic hair stage:

1-5

45.

Female Tanner Staging

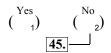
41. Breast stage:

1-5

42. Pubic hair stage:

1-5

43. Has menarche occurred:



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

age in years

PE - Physical Examination

E. Administrative information

45. Study Physician PIN:

46. Study Physician signature:

47. Clinical Coordinator PIN: ____ ___

48. Clinical Coordinator signature:

49. Date form reviewed:

day mon year

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	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix} \\ \begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
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 elbow extended and arm		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 circumfe you have two within 1.5	rence measurements until 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):

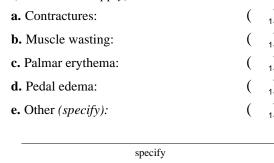
	cm		
b. Splenomegaly:		(1
c. Other (specify):		(1

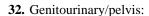
specify

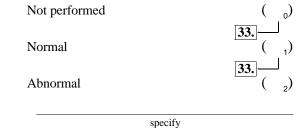
30. Extremities:

Not performed	()
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):

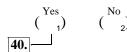
Yes, participant has not reached full sexual maturity or is 17 years old or younger: No, participant is 18 years old or older

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

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 Ethnic cotogow (chan the national ground 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-	
<u> </u>	category that best describes their Hispanic, Lat-	
day mon year	ino, or Latina origin; check only one):	
5. Visit code: _s1	Mexican (1)	
	Puerto Rican (2)	
6. Form & revision:g1	Cuban (3)	
W 1 VIIII W 14 1010 III	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: (1)	
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 Card #3 and ask the respondent to pick the category that describes the patient best; check only one):			22.	22. Combined annual income before taxes of all members of patient's household (show the patient/parent Flash Card #6 and ask the respondent to pick the category that describes the patient's combined household income best;			
	Never attended school	(0)		check only one):	ome 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	,	,		$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$	(No \
	education or training	(6)			28. —	2 <i>)</i>
	Bachelor's degree or higher	(7)		Ŀ	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	(
19.	About how many hours does the patient	t			30-39 years	(2) 3)
	work each week:	- 			40-49 years	(4)
		# hour	S		50-59 years	(5
20.	Which of the following categories best 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.	60 years or older 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 #& ian is	₆) 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	((ر
	specify						47
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	(2)				
	Separated, divorced, or annulled	Ì	3)				
	Widowed	(4)				
		(4/				

26.	Current age of patient's father, stepfather, or male guardian (show patient/parent Flash Card #7; check only one):			E. Previous registration in a NASH CRN study29. Has the patient ever been assigned an ID	
	Not applicable (father is deceased or patient has no stepfather or male			number in a NASH CRN study:	
	guardian)	(0	$\begin{pmatrix} \text{Yes} & \begin{pmatrix} \text{No} \\ 1 \end{pmatrix} & \begin{pmatrix} \frac{\text{No}}{2} \end{pmatrix} \end{pmatrix}$	
	19 or younger	Ò	1)	33.	
	20-29 years	$\tilde{}$	2)		
	30-39 years	(3)	30. In which NASH CRN studies has the	
	40-49 years	(3) 4)	patient previously been registered (check all that apply)	
	•	(()	
	50-59 years	(5)		
	60 years or older	(6)	b. TONIC: (1)	
27.	Highest educational level achieved by patient's father, stepfather, or male	and #	0. <i>;f</i>	c. Other, (specify):	
	guardian (show patient/parent Flash Coeducation of father or male guardian is a record as "n"; check only one):	ira #6 unkno	ovn,	specify	
	Never attended school	(0	31. ID Number previously assigned to patient (record patient ID in item 2):	
	Did not complete high school	(1)	puttent 115 in tiem 2).	
	Completed high school	Ì	2)		
	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	(3) 4)		
	ource of patient (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	(((((((((((((((((((01) 02) 03) 04) 05) 06) 07) 08)	 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. 	
	Pediatric clinic	(₀₉)	G. Administrative information	
	Pediatric weight disorders clinic	(11)	34. Clinical Coordinator PIN:	
	Primary care clinic	(12)		
	Self referral	(13)	35. Clinical Coordinator signature:	
	Other, (specify):	(14)		
	specify			36. Date form reviewed: day mon year	