STOP-NAFLD

AD – Alcohol Use Disorders Identification Test (AUDIT)

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

When: Visit s.

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 family. Clinical Coordinator/parent can assist patients age 8-12.

Instructions: Flash Card #11, Drink Equivalents, may be used with this form. The Clinical Coordinator should complete section A below and write the patient ID on pages 2-3. If the form is self-administered by the patient, the patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator then should complete section B below.

A. Ce	enter, patient, and vi	sit identification		dministrative information To be completed by Clinical Coordinator after	
1.	Center ID:			urvey is completed.)	
2.	Patient ID:		8.	How was the questionnaire completed:	
3.	Patient code:			Self-administered by patient ((
4.	Date of visit (date p	patient completed the form):		10.	
	-	_		Interview in English (2	()
	day	mon year		Interview with translator (3	3)
5.	Visit code:	<u>s</u>	9.	Who was the respondent (check all that apply):	
6.	Form & revision:	a d 1		a. Patient:	(
-)
7.	Study:	STOP-NAFLD <u>9</u>)
				specify	_
			10.	Clinical Coordinator	
				a . PIN:	
				b . Signature:	
					_
			11.	Date form reviewed:	
				day mon year	_

AD – Alcohol Use Disorders Identification Test (AUDIT)

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

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

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

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

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

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

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

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

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

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
(0	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(3)	(4)

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
()	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(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
()	$\begin{pmatrix} & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	(3)	(4)

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

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

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
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

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
$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

22. Today's date:

Thank you for completing this questionnaire.

AE - Adverse Event Report

Purpose: To document an adverse event that threatens the integrity of the STOP-NAFLD trial or well-being of a study participant that includes, but is not limited to:

- (1) events that impact the patient's treatment or participation in STOP-NAFLD
- (2) adverse events that may or may not be related to study drug
- (3) other events that clinical center staff feel should be reported
- (4) when a follow-up report is needed for a previously completed AE form

As defined by Title 21 Code of Federal Regulations Part 312.32 *IND Safety Reporting*: *Adverse event* means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

Serious adverse event or serious suspected adverse reaction. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Other medical events may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Life-threatening adverse event or life-threatening suspected adverse reaction. An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

When: Visits f02, f04, f12, f24, and f36. Use visit code if reporting an event discovered during a regular follow-up visit. Use visit code n if event is discovered between study visits. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code for first event, n for second event, n2 for third event, etc. Adverse events that are serious, unexpected and have reasonable possibility of being caused by STOP-NAFLD study drug should also be recorded on the Serious Adverse Event/IND Safety Report (SR) form.

Completed by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for every visit. The short name (item 19) and the severity grade (item 20) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v5.0 (CTCAE). The CTCAE document is available at www.nashcrn.com. Click on Studies and then STOP-NAFLD. Fax the DCC (Fax 410-955-0932; Attention: Pat Belt) a copy of this form if severity grade is 3 or higher within 1 week for further review by Mariana Lazo, the NASH CRN Safety Officer. For more information, see SOP I sections 6.18 and 6.19.

Follow-up report: A follow-up report should be filed (use this form) when the adverse event is resolved or if there has been a significant change in the patient's condition or in the physician's judgment about the event since the previous report was filed.

A. Center, patient, and visit identification	5. Visit code:	5. Visit code: if report not associated with a visit, fill in "n"		
1. Center ID:	- <u> </u>	ca with a visit, juit in "i		
2. Patient ID:	6. Form & revision:	<u>a</u> <u>e</u> <u>1</u>		
3. Patient code:	7. Study:	STOP-NAFLD 9		
4. Date of report:				
	 ⁄ear			

B. Visit interval identification

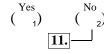
8.	Since the last visit, has the patient had a
	reportable event:

(Y	es 1)	(No 2))
		33.	

9. Most recently completed visit prior to adverse event

a. Date:			
	day	mon	year

- **b.** Visit code: ____ ___
- **10.** Since the last visit, has the patient had any ER visits or hospitalizations:



If Yes, specify reason and list dates:

If none for items 10a or 10b, enter "00".

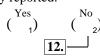
a. Number of hospitalizations:

hospitalizations

b. Number of Emergency Room visits:

visits

11. Since the last visit, has the patient had any health problems not already reported:



If Yes, specify health problem and list dates:

C. Patient information

12. Gender:

Male (1. Female (2.

13. Age at time of event:

years

D. Event description

14. Is this the first report or a followup report for this adverse event:

First report (1)
Followup report (2)

15. Date event started:

<u>=_</u>		
day	mon	year

16. Nature of event (check all that apply)

a. Drug dispensing mixup: $\binom{1}{1}$

b. Medication related event: (1)

c. Study procedure related event:

d. Severe allergic reaction: (₁) **e.** Drug interactions: (₁)

f. Worsening of a co-morbid illness:

g. Patient reported symptom of

hepatotoxicity: (1)

h. Gastrointestinal symptoms: (1)

i. Diabetes:

j. Pregnancy (patient): (*₁)

k. Other (specify):

*STOP-NAFLD study drug will be discontinued if a patient becomes pregnant. Contact the NASH CRN Data Coordinating Center to unmask the study drug.

17. Describe event:

For items 18, 19, and 20, please refer to CTCAE v5.0 available at www.nashcrn.com; click on Studies and then STOP-NAFLD.

18. Identify body system (*check all that apply*)

a. Auditory/ear:	(1/
b. Allergy/immunologic:	(1/
c. Ocular/visual:	(1/
d. Hepatobiliary/pancreatic:	(1/
e. Infection:	(1
f. Constitutional symptoms:	(1/
g. Psychiatric:	(1/

- h. Cardiovascular:
- i. Dermatologic/skin:

 j. Endocrine/metabolic:

 k. Gastrointestinal/digestive:

 l. Lymphatic/blood:

 (1)
- m. Musculoskeletal: (1)
 n. Neurologic: (1)
- o. Pulmonary/respiratory:
 p. Renal/genitourinary:
 q. Sexual/reproductive:
 1)
 q. 1)
- r. Other (specify):

 specify other body system

	specify other body system		
s.	None of the above:	(1)

19. Is the event listed in the NCIs Common Terminology Criteria for Adverse Events (CTCAE v5.0):

Y	es	N	Ю
(1)	(2)

a. Indicate the name of the event (if in the CTCAE, specify name exactly from document; if not in CTCAE specify name): **20.** Indicate the severity code using the CTCAE grading scale for the AE specified (*severity grades are listed in the CTCAE v5.0 document*):

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

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

- *Complete and key Death Report (DR) form.
- 21. Randomization in STOP-NAFLD
 - **a.** Has patient been randomized in STOP-NAFLD:

(Y	es 1	(1	No 2)
		29.	J
)P-NAF	ПD		

b. Date randomized in STOP-NAFLD:

_		_
day	mon	year

22. Is the patient currently receiving the STOP-NAFLD study drug:

- **23.** Patient's history of treatment with STOP-NAFLD study drug
 - **a.** How long has patient been on study drug:
 - **b.** What daily dose was the patient taking prior to the adverse event:

	mg/dav	

Nο

c. Have there been any treatment interruptions or restarts:

Include stop/restart dates a	(1) and reasons:	(2)

24.	Is there evidence to suggest a causal relationship between the STOP-NAFLD			29. Current status of adverse event (<i>check only one</i>):
	study drug and the adverse event:			Resolved (
	Definitely yes	(1)	Active
	Probably yes	(2)	31.
	Possibly yes	(3)	Unknown
	Probably no	(4)	31.
	Definitely no	(5)	30. Date adverse event resolved:
25.	Is this a serious adverse event:			<u> </u>
	(Yes	(No 2)	day mon year 31. What action was taken:
	If Yes, then select all the reasons that app		_	
	a. Severity Grade 4 or 5:	(1)	
	b. Required inpatient hospitalization or prolonged existing hospitalization:	(1)	
	c. Persistent or significant incapacity or substantial disruption of ability to conduct normal life functions:	(1)	
	d. Jeopardized patient and required medical or surgical intervention to prevent a serious event:	(1)	32. Other comments on event:
	e. Congenital anomaly or birth defect:	(1)	
26.	Is this an unexpected adverse event:			
	Yes	1	No \	
	(1)	_ (₂)	
	28	<u> </u>		
27.	Reason the adverse event was			E. Administrative information
	unexpected:			33. Clinical Coordinator PIN:
	Not listed in the losartan potassium investigator's brochure	(1)	34. Clinical Coordinator signature:
	Listed in the losartan potassium investigator's brochure, but not at the specificity or severity that has been			
	observed	(2)	35. Study Physician PIN:
	Listed in the losartan potassium investigator's brochure as anticipated from the pharmacological properties of the study drug, but is not specifically mentioned as occurring with previous			36. Study Physician signature:
	experience of losartan potassium	(3)	37. Date form reviewed:
28	Did you select "Yes" for items 24			
-0.	(definitely, probably, or possibly), 25, and 26:			day mon year

Key this form and fax the DCC (Attention: Pat Belt) a copy of this form if severity grade is 3 or higher. We are asking for copies of these reports on serious adverse events so that we assure appro-priate and timely NIDDK review. The serious adverse event reports will be reviewed by Mariana Lazo, the Safety Officer.

instructions.

*If Yes, please also complete a Serious Adverse Event/IND Safety Report (SR) form and follow

BH - Baseline History

Purpose: To collect baseline history information about the patient.

When: Visit s.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient or patient's parent.

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

A.	Center,	visit,	and	patient	identification

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

=		_
day	mon	year

5. Visit code:

- **6.** Form & revision:
- STOP-NAFLD 9

B. NAFLD history

7. Study:

8. Does the patient have a liver biopsy done that you want evaluated for the STOP-NAFLD trial (complete the Liver Biopsy Histology Findings (HF) and Liver Biopsy Materials Documentation (SD) forms for this biopsy):

*Randomization must be done within 730 days of liver biopsy.

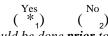
9. Date of liver biopsy:

day	mon	year

10. Last day to randomize based on liver biopsy date or registration date (730 days after biopsy or 60 days after registration date; use date calculator 2 on the NASH CRN home page; enter earliest date):

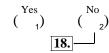
day	mon	year

11. Will the patient have a biopsy during screening:



*Blood draw for banking should be done **prior** to the biopsy or at least 4 days **after** the biopsy.

- C. Tobacco cigarette smoking history (interview with patient; not interview with parent, not by chart review)
- **12.** Is the patient age 12 or older:



13. Have you ever smoked tobacco cigarettes:

Never (1)

In the past but not anymore (2)

Currently smokes cigarettes (3)

14. 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):



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

years

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

years

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

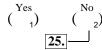
cigarettes/day

D. Menstrual history and use of effective birth control

18. Is the patient female:

Y	es		No
(1)	(2)
		25. —	

- 19. Menarche history
 - a. Has menarche occurred:



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

age in years

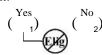
20. Characterize the menstrual history in the past year (*check only one*):

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

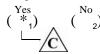
21. Is the patient of childbearing potential:



22. Is the patient currently pregnant:

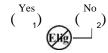


23. Is the patient currently breastfeeding:



*Caution: Patient cannot be breastfeeding at time of randomization.

24. If sexually active, is the patient willing to use two effective birth control methods during STOP-NAFLD:



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

a. Diabetes type 1: $\binom{*}{1}$

b. Diabetes type 2: (*₁)

*If HbA1c is \geq 9.5%, patient is ineligible.

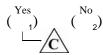
- c. Hepatitis B:
- **d.** Hepatitis C:
- e. Autoimmune hepatitis:
- f. Autoimmune cholestatic liver disorder (PBC or PSC):
- g. Wilson's disease:
- h. Alpha-1-antitrypsin (A1AT) deficiency:
- i. Hemochromatosis or iron overload:
- **j.** Drug induced liver disease:
- k. Ascites:
- **l.** Gilbert's syndrome: (1)
- **m.** Esophageal or gastric varices on endoscopy:
- **n.** Bleeding from varices:

 Gastrointestinal ulcers or other gastrointestinal bleeding: 	(1)	aj. Hyperlipidemia (high cholesterol, high triglycerides):	(1)
	∕c\ ⊸	ak. Pancreatitis:	(1)
p. Biliary diversion:	(,)	al. Cholelithiasis:	(1)
	(C) ↓	am. Coronary artery disease:	(1)
a Matabalia acidosis:	()	an. Elevated uric acid such as gout:	(1)
q. Metabolic acidosis:		ao. Kidney disease:	(1)
	<u>/C</u> \•		∕c\•	
r. Edema:	(₁)	ap. Polycystic ovary syndrome:		1)
	<u>\C</u> \•	aq. Sleep apnea:	ì	1)
s. Hepatic encephalopathy:	(₁)	ar. Dermatologic disorders:	(1)
	$\overline{\mathbf{c}}$	as. Myopathy:	(1)
t. Any other evidence of chronic liver		at. Myositis:	(1)
disease:	(₁)	au. Major depression:	(1)
	∠C∖◆□	av. Schizophrenia:	(1)
u. Short bowel syndrome:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	aw. Bipolar disorder:	(1)
v. Hemophilia (bleeding disorder):	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	ax. Obsessive compulsive disorder:	ì	1)
w. Systemic autoimmune disorder sucl as rheumatoid arthritis or systemic lupus:	h (₁)	ay. Severe anxiety or personality disorder:	(1)
x. Endocrine disease	(1)	az. Substance abuse:	(1)
(hormonal abnormality):	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$		_C\ ←]
y. Asthma:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	ba. None of the above:		1)
z. Hepatocellular carcinoma:	(1)			17
	€	26. Has the patient ever had bariatric surg for any of the following (check all that	ery (ery)	
aa. Other malignancy (cancer):	(₁)	a. Stapling or banding of the stomach	: (Erg	₁)
ab. Human immunodeficiency virus (HIV):	(₁)	b. Jejunoileal (or other intestinal) bypass:	((() () () () () () () () ()	₁)
ac. Peripheral neuropathy:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	c. Biliopancreatic diversion:	(1)
ad. Seizure disorder or epilepsy:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	1	(Elig)—] '
ae. Drug allergies:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	d. Other bariatric surgery (<i>specify</i>):	0)
af. Hypothyroidism:	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$	u. Other barrathe surgery (specify).	Δ'	- 1ノ
ag. Stage 2 hypertension:	(1)		<u> </u>	7
	<u>C</u>			
ah. Hypotension or orthostatic	, ,	e. None of the above:	(1)
hypotension:	(₁)	27. Is the patient currently undergoing evaluation for bariatric surgery:		
ai. Cerebrovascular disease:	(1)	(Yes		¹⁰ ₂)

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

28. Has the patient received total parenteral nutrition (TPN) in the past year:

- 29. Organ, limb, or bone marrow transplant
 - **a.** Has the patient ever received a liver transplant:



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

3	/es	N	o
(1)	(2)

F. Drugs historically associated with NAFLD

30. Has the patient used any tetracyclines, salicylates, valproic acid or other known hepatotoxins in the past year (check all that apply)

a. Amiodarone (Pacerone): (1.)
------------------------------------	----	---

- **b.** Demeclocycline (Declomycin): (1)
- **c.** Divalproex (Depakote):
- **d.** Doxycycline (Monodox):
- **e.** Isonicotinylhydrazine (INH, Isoniazid, Tubizid): (1)
- **f.** Isotretinoin (Accutane, Amnesteem, Clarvis, or Sotret): (1
- **g.** Methotrexate (Rheumatrex): (,)
- **h.** Minocycline (Dynacin, Minocin):
- i. Oxytetracycline (Terramycin):
- **j.** Tetracycline (Achromycin):
- **k.** Valproate sodium (Depacon):
- **l.** Valproic acid (Depakene):
- **m.** Other known hepatotoxin (specify):

n.	None of the above:	(1/

31. Were any of the items in 30a-m checked:

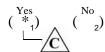


* Caution: Use of any of these drugs for more than 2 consecutive weeks in the past year is exclusionary

32. Has the patient taken any systemic glucocorticoids in the past year (*check all that apply*)

a. Betamethasone sodium (Celestone): $\binom{1}{1}$

- **b.** Cortisol: (1)
- **c.** Cortisone: (1)
- **d.** Dexamethasone (Decadron): (1)
- **e.** Hydrocortisone (Hydrocortone): (1)
- **f.** Methylprednisolone (Solu-Medrol):
- g. Prednisolone (Prelone):
- h. Prednisone: (1)
- i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort):
- **j.** Other, (specify):
- **k.** None of the above:
- **33.** Were any of the items 32a-j checked:



*Caution: Use of systemic glucocorticoids for more than 2 consecutive weeks in the past year is exclusionary.

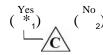
34. Has the patient taken any estrogens at doses greater than those used for hormone replacement for more than two weeks in the past year:



35.	Has the patient taken any anabolic
	steroids or tamoxifen in the past year
	(check all that apply)

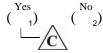
a.	Boldenone undecylenate (Equipoise):	(1)
----	-------------------------------------	---	----

36. Were any of the items 35a-k checked:



*Caution: Use of anabolic steroids or tamoxifen for more than 2 consecutive weeks in the past year is exclusionary.

37. Does the patient have a known allergy to losartan potassium or other angiotensin receptor blocker:



G. Use of antidiabetic drugs

38. Has the patient used any antidiabetic medications in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	39.

(If yes, check all that apply)		
a. Acarbose (Precose):	(1)
b. Acetohexamide (Dymelor):	(1)
c. Albiglutide (Tanzeum, Eperzan)	(1)
d. Alogliptin (Nesina)	(1)
e. Bromocriptine mesylate (Cycloset)	(1)
f. Canagliflozin (Invokana)	(1)
g. Chlorpropamide (Diabinese):	(1)
h. Dapagliflozin (Farxiga)	(1)
i. Dulaglutide (Trulicity)	(1)
j. Empagliflozin (Jardiance)	(1)
k. Exenatide (Byetta, Bydureon)	(1)
l. Gliclazide (Diamicron MC)	(1)
m. Glimepiride (Amaryl):	(1)
n. Glipizide (Glucotrol, Glucatrol XL):	(1)
o. Glipizide/Metformin (Metaglip)	(*1)
p. Glyburide (Micronase, DiaBeta, Glynase):	(1)
q. Glyburide/Metformin (Glucovance)	(*1)
r. Insulin:	(1)
s. Linagliptin (Tradjenta)	(1)
t. Liraglutide (Victoza)	(1)
u. Lixisenatide (Lyxumia)	(1)
v. Metformin (Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet):	(*,)
w. Miglitol (Glycet):	(1)
x. Nateglinide (Starlix):	(1)
y. Pioglitazone (Actos):	(1)

* New treatment with metformin or drugs containing metformin started in past 90 days or plans to alter dose or stop over next 24 weeks is exclusionary. Stable dose is acceptable.

z. Pioglitazone/Glimepiride (Duetact)

aa. Pioglitazone/Metformin (ActoPlus Met, ActoPlus Met XR)	(*1)
ab. Repaglinide (Prandin):	(1)
ac. Repaglinide/Metformin (PrandiMet)	(* 1)
ad. Rosiglitazone (Avandia):	(1)
ae. Rosiglitazone/Glimepiride (Avandryl)	(1)
af. Rosiglitazone/Metformin (Avandamet)	(*,)
ag. Saxagliptin (Onglyza)	(1)
ah. Saxagliptin/Metformin (Kombiglyze XR)	(*,)
ai. Sitagliptin (Januvia)	(1)
aj. Sitagliptin/Metformin (Janumet)	(*1)
ak. Tolazamide (Tolinase):	(1)
al. Tolbutamide (Orinase):	(1)
am. Vildagliptin (Galvus, Zomelis)	(1)
an. Other, (specify):	(1)

^{*} New treatment with metformin or drugs containing metformin started in past 90 days or plans to alter dose or stop over next 24 weeks is exclusionary. Stable dose is acceptable.

H. Use of supplements, vitamins, and other drugs

39. Has the patient taken any of the following supplements/drugs in the past 6 months:

pasi o monins.		
$\binom{\mathrm{Yes}}{1}$	(N	0 2
	40.	ļ
(If yes, check all that apply)		
a. Betaine (Cystadone):	(1)
b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler):	(1/
c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol):	(1)
d. S-Adenylmethionine (SAM-e):	(1)
e. Milk thistle:	(1)
f. Probiotics:	(1)
g. Other (specify):	(1)

specify

40. Has the patient taken any vitamins or minerals in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & 2 \end{pmatrix}$
	41.

(If yes, check all that apply)

h. Other, (specify):

a. Vitamin A:	(1)
b. Vitamin B (any type):	(1)
c. Vitamin C:	(1)
d. Vitamin D:	(1)
e. Vitamin E:	(* ₁)
f. Multivitamin:	(1)
g. Potassium (any form):	(†₁) (†₁)

^{*} New treatment/dose with vitamin E started in past 90 days or plans to alter or stop over next 24 weeks is exclusionary. A stable dose is acceptable.

[†] Current treatment with potassium supplements is exclusionary.

I. Use of statins, fibrates, and antiobesity drugs

41. Has the patient taken any lipid-lowering medications in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
	42.

(If yes, check all that apply)

a. Amlodipine/atorvastatin (Caduet):	(1)
b. Atorvastatin (Lipitor):	(1)
c. Colestipol hydrochloride (Colestid):	(1)
d. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate):	(1)
e. Ezetimibe/atorvastatin (Liptruzet):	(1)
f. Ezetimibe/simvastatin (Vytorin):	(1)
g. Fenofibrate tablets or micronized (Fenoglide, Lipofen, Lofibra tablets, Tricor, Triglade, Antara, Lofibra capsules):	(1)
h. Fluvastatin sodium (Lescol, Lescol XL):	(1)
i. Gemfibrozil (Gen-Fibro, Lopid):	(1)
j. Lovastatin (Altoprev, Mevacor):	(1)
k. Niacin/lovastatin (Advicor):	(1)
l. Nicotinic acid (Niaspan):	(1)
m. Pitavastatin (Livalo):	(1)
n. Pravastatin sodium (Pravachol):	(1)
o. Rosuvastatin (Crestor):	(1)
p. Simvastatin (Zocor):	(1)
q. Sitagliptin/simvastatin (Juvisync):	(1)
r. Other, (specify):	(1)

42. Has the patient taken any antiobesity medications in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
, 17	1
	43.

(If yes, check all that apply)

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

I. Use of other medications and supplements

43. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
	45.

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

44. Is the patient taking non-steroidal anti-inflammatory medications (NSAIDs) daily:



45. Has the patient taken any histamine H2 receptor antagonists or other gastrointestinal medications in the past 6 months:

Y	es	1	No
(1)	(2)
		46. —	J

(If yes, check all that apply)

(2) yes, entern an inter approx		
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.

Has the patient taken any
antihypertensive medications in the past
6 months:

Yes	No
$(*_1)$	(
` ' /	` 2
<u> </u>	2/

(I) yes, check an mai apply)		
a. Amlodipine besylate (Norvasc):	(1)
b. Atenolol (Tenormin):	(1)
c. Benazepril (Lotensin):	(1)
d. Bisoprolol (Zebeta):	(1)
e. Candesartan cilexetil (Atacand):	(1)
f. Captopril (Capoten):	(1)
g. Chlorthalidone (Thalitone):	(1)
h. Clonidine (Catapres):	(1)
i. Diltiazem (Cardizem):	(1)
j. Doxazosin (Cardura):	(1)
k. Enalapril (Vasotec):	(1)
l. Felodipine (Plendil):	(1)
m. Fosinopril (Monopril):	(1)
n. Furosemide (Lasix):	(1)
o. Hydrochlorothiazide (Esidrix, HydroDIURIL):	(1)
p. Hydrochlorothiazide + triamterene (Dyazide):	(1)
q. Irbesartan (Avapro):	(1)
r. Isadipine (DynaCirc, Prescal):	(1)
s. Lisinopril (Prinivil, Zestril):	(1)
t. Losartan potassium (Cozaar):	(1)
u. Losartan potassium with hydrochlorothiazide (Hyzaar):	(1)
v. Metoprolol (Lopressor):	(1)
w. Nifedipine (Adalat, Procardia):	(1)
x. Olmesartan (Benicar):	(1)
y. Prazosin (Minipress):	(1)
z. Propranolol (Inderal):	(1)
aa. Quinapril (Accupril):	(1)
ab. Ramipril (Altace):	(1)
ac. Terazosin (Hytrin):	(1)
ad. Timolol maleate (Blocadren):	(1)
ae. Valsartan (Diovan):	(1)
af. Verapamil (Calan):	(1)

^{*} Current treatment with any antihypertensive medication is exclusionary.

47. Has the patient taken any cardiovascular medications in the past 6 months:

Y	es	1	Vо
((۱	((ر
`	17	`	1 2
		48. —	_

(If yes, check all that apply)

- a. Digoxin (Lanoxin): (1)
 b. Perhexiline maleate: (1)
 c. Other, (specify): (1)
- **48.** Has the patient taken any allergy or asthma medications in the past 6 months:

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

(If yes, check all that apply)

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

49. Has the patient taken any antipsychotic or antidepressant medications in the past 6 months:

Yes	No
(₁)	(2
	51.

- **a.** Aripipazole (Abilify): (1)
- **b.** Buporpion (Wellbutrin):
- **c.** Clomipramine (Anafranil): (1)
- **d.** Escitalopram (Lexapro):
- e. Fluoxetine (Prozac):
- **f.** Fluvoxamine (Luvox):
- **g.** Lithium (Eskalith, Lithobid): (1) **h.** Quetiapine (Seroquel): (1)
- i. Risperidone (Risperdal):
- j. Sertraline (Zoloft):
- **k.** Other (specify):
- **50.** Is the patient currently being treated with lithium:

	Yes	N	lо
(1)	(2
	—(E)ig)	

51. Has the patient taken any supplements in the past 6 months that have not already been reported on this form:

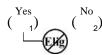
Yes	No
(₁)	(2)
	52.

(If yes, check all that apply)		
a. Alpha-lipoic acid:	(1)
b. Beta-carotene:	(1)
c. Calcium (any form):	(1)
d. Carnitine (any form):	(1)
e. Chondroitin (any form):	(1)
f. Cod liver oil:	(1)
g. Coenzyme Q:	(1)
h. Dichloroacetate:	(1)
i. Echinacea:	(1)
j. Fish oil (any form):	(1)
k. Flax seed oil:	(1)
l. Garlic:	(1)
m. Ginkgo biloba:	(1)
n. Glucosamine (any form):	(1)
o. Lecithin:	(1)
p. Magnesium:	(1)
q. N-acetyl-cysteine:	(1)
r. Saw palmetto:	(1)
s. Selenium:	(1)
t. St. John's Wort:	(1)
u. Taurine:	(1)
v. Zinc picolinate:	(1)
w. Other, (specify):	(1)

52. Has patient taken any of the following medications in the past 6 months:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
	53.

- **a.** Levonorgestrel (Norplant):
- **b.** Levothyroxine (Levoxyl, Synthroid):
- **c.** Liothyronine (Cytomel): (1)
- **d.** Oral contraceptives:
- e. Penicillamine (Cuprimine, Depen):
- **f.** Trientine hydrochloride (Syprine):
- **g.** Other, (specify):
- **h.** Other, (specify):
- i. Other, (specify):
- **j.** Other, (specify):
- **k.** Other, (specify):
- **53.** Has the patient participated in an IND trial in the past 150 days:



- J. Administrative information
- **54.** Study Physician PIN:
- **55.** Study Physician signature:
- **56.** Clinical Coordinator PIN: ____ ____
- **57.** Clinical Coordinator signature:
- **58.** Date form reviewed:

BL - Blood Pressure Log Documentation

Keyed: ()

Purpose: To document completion of the blood pressure log.

When: Visit f04; use visit code n if returned at visit other than f04.

By whom: Clinical Coordinator.

Instructions: The STOP-NAFLD Blood Pressure Log should be given to the child at the randomization visit with the blood pressure monitor after giving instructions to the family on how to obtain and record the blood pressure readings. This form should be completed and keyed after the return of the blood pressure log at the week four visit. If the patient forgets to return the log at the f04 visit, a photo of the log is acceptable. Staple the completed Blood Pressure Log to this form. Note that the information on the blood pressure log is not keyed. If any blood pressure excursions (high or low) are noted email a copy of this form and Blood Pressure Log to Pat Belt at the DCC (pbelt@jhu.edu).

A. Center, patient and visit identification	11. Number of days with elevated blood pressure (systolic BP greater than 140
1. Center ID:	mm/Hg or diastolic BP greater than 90 mm/Hg):
2. Patient ID:	*
	(00-14)
3. Patient code:	*If one or more, email this form and the Blood Pressure Log to Pat Belt at the DCC (pbelt@jhu.edu).
4. Date form completed:	
day mon year	12. Number of days with low blood pressure (systolic BP less than 90 mm/Hg or diastolic BP less than 60 mm/Hg):
5. Visit code:	diasone 21 1000 than 00 min 120).
	<u>*</u> (00-14)
6. Form & revision:b12_	*If one or more, email this form and the Blood
7. Study: STOP-NAFLD 9	Pressure Log to Pat Belt at the DCC (pbelt@jhu.edu).
B. Blood pressure log information	13. Were any adverse events related to blood
8. Blood pressure cuff given to patient:	
Arm (1)	pressure reported: ${\text{Yes} \choose 1}$ ${\text{No} \choose 2}$
Wrist (₂)	C. Administrative information
9. Was the blood pressure log returned or was a photo of the log obtained:	14. Clinical Coordinator PIN:
$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$	15. Clinical Coordinator signature:
14.	
* Remind patient to bring log to next visit. a. Date log returned:	16. Date form reviewed:
day mon year	day mon year
10. Number of days blood pressure recorded:	
(00-14)	

BP - Blood Processing for Plasma and Serum

Purpose: Document collection of fasting blood for separation of plasma and serum.

When: Visits s, f12, f24, and f36.

By whom: Clinical Coordinator and laboratory personnel responsible for collection and processing of blood.

Instructions: Label tubes of blood using MACO labels specific for the patient and visit; these labels are generated by the clinical center upon registration (screening visit labels) or after enrollment (follow-up visit labels). Attach duplicate blood tube labels in items 11 and 13. Choose one of the cryovial label sets provided by the DCC for this patient for use with this visit. Label 2.0 mL cryovials with numbered patient-specific plasma (blue-top) and serum (red-top) cryovial labels provided by the DCC. Affix plasma aliquot #00 label and serum aliquot #00 label to this form in item 18. If blood was previously collected for the NAFLD Database 2 and is being used for STOP-NAFLD, transcribe the data from the Database 2 BP form, including the cryovial label information, and attach that form to the STOP-NAFLD BP form. If blood is not collected at the screening visit, the child is not eligible for STOP-NAFLD unless previously collected samples are available.

For plasma: Fill <u>one</u> 10 mL green top heparin tube with blood. Process blood for plasma within 30 minutes according to procedures specified in the STOP-NAFLD SOP I, section 6. After separation, prepare up to 10 aliquots of plasma: pipette 0.5 mL of plasma to each prelabeled 2.0 mL cryovial. Immediately freeze labeled aliquots of plasma at -70 C.

For serum: Fill <u>two</u> 10 mL SST red-gray top tubes with blood. Process blood for serum within two hours according to procedures specified in the STOP-NAFLD SOP I, section 6. After separation, prepare up to 20 aliquots of serum: pipette 0.5 mL of serum to each prelabeled 2.0 mL cryovial. Immediately freeze labeled aliquots of serum at -70 C.

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 determined.

A. Center, patient and vis	it identification
1. Center code:	
2. Patient ID:	
3. Patient code:	
4. Date of visit:	
day	mon year
5. Visit code:	
6. Form & revision:	_bp1_
7. Study:	STOP-NAFLD 9

B. Processing whole blood

Plasma and serum aliquots are to be separated from blood per instructions in the SOP I. Draw fasting blood in the morning.

8. Was participant fasting for at least 8 hours* prior to blood draw:

Yes No (1) (2) *A 12-hour fast is preferred, but will accept non-fasting samples.

a. Was blood collected for the NIDDK Biosample Repository:

140, (specify).	23.
No, (specify):	(\dagger_3)
Database 2	$(*_{2})$
Yes, previously collected for NAFL	
Yes	(1)

specify reason

*If using blood collected for NAFLD Database 2, transcribe Database 2 BP form to this form and attach a copy. NOTE: Samples from DB2 must have been collected within 60 days of visit date.

†Blood collection is required at the screening visit unless samples previously collected for Database 2 are being used; do not key form. If patient did not come to clinic for follow-up visit, complete the MV form instead of the BP form.

_						
9.	Date	and	time	of bl	lood	draw

a. Date:

day	mon	year

b. Time:

	:	(1)	(,
hour	minute	am	pm

10. Number of heparin (green-top) tubes:

11. Affix matching heparin tube MACO label (only key NASH ID):

STOP-N	VAFLD Form BP,
BP Plas	ma.
Pt:	9999, xyz
Visit	VVV
Date: _	

12. Number of SST serum separator (red-gray top) tubes:

13. Attach duplicate SST serum separator tube labels (*only key NASH ID*):

STOP-NAFLD Form BP,
Serum 1
Pt: 9999, xyz
Visit: vvv
BP
Date:

STOP-NAFLD Form BP, Serum 2 Pt: 9999, xyz Visit: vvv BP Date:

14. Phlebotomist:

print name

C. Aliquots for plasma and serum

Pipette 0.5 mL of plasma into each of up to ten 2.0 mL pre-labeled cryovials and pipette 0.5 mL of serum into each of up to 20 2.0 mL pre-labeled cryovials.

15. Date and time of separation into plasma and serum aliquots

a. Date:

day	mon	year

b. Time of plasma separation:

	:	(,)	(,
hour	minute	am	pm
Time of se	rum separation:		

c. Time of serum separation:

	:	(1)	(,
hour	minute	am	pm

16. Number of aliquots for plasma: ____ _

17. Number of aliquots for serum: _____

18. Attach duplicate cryovial labels (use aliquot #00 labels which are located in the first row of labels in the set):

Serum aliquot #00 label	Plasma aliquot #00 label

19. Technician:

- 1	
	print name

D. Freezing aliquots

Freeze plasma and serum aliquots immediately at -70°C or -20°C. If frozen at -20°C, the cryovials must be transferred to -70°C within 24 hours. Batch ship monthly to the NIDDK Biosample Repository at Precision for Medicine.

20. Date and time cryovials frozen in -70°C or -20°C

a. Date:

a. Date:

b. Time:

	:	(1)	(2)
hour	minute	am	pm

- **21.** Number of cryovials frozen: ____ __
- 22. Technician:

print name

- E. Administrative information
- 23. Clinical Coordinator PIN: ____ ___
- **24.** Clinical Coordinator signature:
- **25.** Date form reviewed:

day	mon	year

BQ – Beverage Questionnaire (BEVQ-15)

Purpose: To obtain the patient's beverage intake.

When: Visits s, f24, and f36.

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

Respondent: Patient or completed by patient with parental assistance.

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

A. Center, patient, and visit identification			n	C. Administrative information		
1.	Center ID:			(To be completed by clinical center staff after surver is completed.)		
2.	Patient ID:			24. Clinical Coordinator PIN:		
3.	Patient code:			25. Clinical Coordinator signature:		
4.	Date of visit:					
	day	mon	year	26. Date form reviewed:		
5.	Visit code:			day mon year		
6.	Form & revision:	<u>b</u>	<u>q</u> <u>1</u>			
7.	Study:	STOP-	NAFLD 9			

1 of 2

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

1) Indicate how often you drank the following beverages,	for example, if you drank 5 glasses of water
per week, circle response "3" under the column label	ed "4-6 times per week".

• •	T 1	1 1 1 2	· 1 1 1 1	
2)	Indicate the approximate amount of beve	erage you drank each time,	for example, you drank I cu	др
	of water each time, circle response "2"	under the column labeled	"8 fl oz (1 cup)" under "hov	v much
	each time.			

3	Do not count	beverages use	ed in cooking	or other pre	eparations,	such as	milk in ce	ereal.

4)	Count milk added to tea and	l coffee in the	tea/coffee with	cream beverage	category NOT	in the milk categories.

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

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

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Affix label here

Patient ID: Patient code: Visit code:

7. Study:

CG - Genetic Consent and Blood Collection Documentation

Purpose: To document consent for collection of blood samples for genetic research and the collection of whole blood for DNA extraction and banking at the NIDDK Genetics Repository.

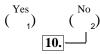
When: Screening visit s or as needed during follow-up due to a low yield (less than 50 μ g) of DNA (during follow-up, use the visit code of the follow-up visit that is open).

By whom: Study Physician, Clinical Coordinator and laboratory personnel responsible for collection of blood. **Instructions**: Complete this form based on the consent documents signed by the patient/parent. If the patient changes his/her mind regarding consent for use of samples after the initial form is completed, complete a new CG form. If the patient consents, (1) Fill one 10 mL EDTA vacutainer tube with blood. (2) Pack and ship the blood in the EDTA tube to RUCDR Infinite Biologics on the same day blood is collected. Ship at ambient room temperature. Ship blood in the specimen shippers supplied by RUCDR Infinite Biologics.

Δ	Center	patient	and '	vicit	identi	fication
A.	Center.	Dauent	anu	VISIL	luchu	ucauon

1. Center ID:			
2. Patient ID:			
3. Patient code:			
4. Date form completed:			
day	mon		year
5. Visit code:			
6. Form & revision:		_c_	_g1_

- B. Consent for collection, storage, and use of blood samples for current and future genetic research
 - 8. Has a sufficient yield of DNA (≥100 micrograms) been banked at the NIDDK Genetics Repository for this participant in a previous NASH CRN study:

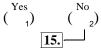


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9. For which study was it collected *(check all that apply):*

a. Database	(1
b. TONIC	(1
c. Database 2	(1
d. CyNCh	(1
e. Other, (specify):	(1)
specify	
	15.

10. In your judgment, has the patient consented to collection of blood for DNA banking (a response of "No" to this question (item 10) means that blood should NOT be collected for sending to the Genetics Repository and if already collected, should be destroyed by the Genetics Repository):



C. Specimen for Genetics Repository

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

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

Yes No, (specify):		12
	specify	
		15.

12.	Date	and	time	αf	blood	draw
14.	Date	anu	unic	OΙ	uloud	uran

a. Date:

day mon year

b. Time:

hour minute

(₁)

 $\binom{2}{pm}$

13. Attach form copy of tube label:

STOP-NAFLD Form CG

Pt: ccc- 9999, xyz

Gender

Age, yrs.: XX

14. Phlebotomist:

print name

D. Administrative information

- **15.** Study Physician PIN:
- **16.** Study Physician signature:
- **17.** Clinical Coordinator PIN: ____ ___
- **18.** Clinical Coordinator signature:

19. Date form reviewed:

day mon year

CO - Closeout Form

Purpose: To close out a patient's participation in STOP-NAFLD and document the patient's consent to join or reenter the NAFLD Database 2 study.

When: At f36 visit or at the close of the f36 window.

Respondent: Clinical coordinator.

Instructions: Complete this form for each patient randomized in STOP-NAFLD at the f36 visit or at the close of the f36 window. Determine if the patient now wants to re-enter or join the NAFLD Database 2. Schedule the patient for a NAFLD Database 2 follow-up visit approximately 12 months from this visit.

(1) Patients previously enrolled in the NAFLD Database 2: consult the NAFLD Database 2 visit schedule generated at NAFLD enrollment and use the visit window that is open in 12 months.

(2) Patients NOT previously enrolled in the NAFLD Database 2: if patient is willing to join the NAFLD Database 2, a visit schedule will be generated upon keying this form. Schedule the participant approximately 12 months from their STOP-NAFLD f36 visit for their t096 NAFLD Database 2 follow-up visit.

Δ	Center	patient	and	vicit	iden	tifica	tion

1. Center ID:				
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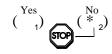
mon

B. Database participation

8. Does the patient/parent wish to re-enter or join the NAFLD Database 2:

year

9. Has the patient/parent signed the latest version of the NAFLD Database 2 informed consent:



^{*} Patient/parent must sign the informed consent

10. Was the patient enrolled in the NAFLD Database 2 previously:



* Schedule the patient's next NAFLD Database 2 follow-up visit approximately 12 months from the date in item 4. Consult the patient's NAFLD Database 2 visit schedule and use the NAFLD Database 2 visit open on that date.

+ Data system will generate a visit window schedule assigning the STOP-NAFLD randomization date as the NAFLD Database 2 enrollment date. Schedule the patient approximately 12 months from the date in item 4 for their t096 NAFLD Database 2 follow-up visit.

C. Administrative information

- 11. Clinical Coordinator PIN:
- 12. Clinical Coordinator signature:

13. Date form reviewed:		
	mon	

Central Histology Review

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

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

By whom: Data Coordinating Center staff.

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

	A. Clinic, patient and visit identification1. Center ID
	2. Patient ID
	3. Patient code
/	4. Date of central reading
	5. Visit code
<u>c r 3</u>	6. Form and revision
	7. Study: 6 =Database 2; 9 =STOP-NAFLD
//	8. Date of biopsy
	B. Slide sequence number9. Sequence number for a. H & E stained slide
	b. Masson's trichrome stained slide
	c. Iron stained slide
	C. Adequacy of biopsy 10. Biopsy length (mm)
<u> </u>	11. Tissue adequate: 0 =No → Request original slides from
	submitting clinic; 1 =Yes
	submitting clinic; 1 =Yes 12. Followup with clinic (<i>Specify</i>):

	1 ditent 1D
	H & E stain
	13. Steatosis (assume macro, e.g., large and small droplet)
	a. Grade: 0 =<5%; 1 =5-33%; 2 =34-66%; 3 =>66%
	b. Location: 0 =Zone 3 (central); 1 =Zone 1 (periportal); 2 =Azonal; 3 =Panacinar
_	c. Type of macrovesicular steatosis: 0 =Predominantly large droplet; 1 =Mixed large and small droplet;
	2=Predominantly small droplet
	d. Microvesicular steatosis, contiguous patches: 0 =Absent; 1 =Present
	u. miero vestediai steatosis, comiguous patenesi o riosem, r riosem
	14. Inflammation
	a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci:
_	0 =0; 1 =<2 under 20x mag; 2 =2-4 under 20 mag; 3 =>4 under 20 mag
	d. Amount of portal, chronic inflammation: 0 =None; 1 =Mild; 2 =More than mild
	15. Liver cell injury
	a. Ballooning: 0 =None → GOTO Item 15d ; 1 =Few; 2 =Many
	b. Severe ballooning present: 0 =No; 1 =Yes
	c. Classical balloon cells present: 0 =No; 1 =Yes
	d. Acidophil bodies: 0 =Rare/absent; 1 =Many
	f. Megamitochondria: 0 =Rare/absent; 1 =Many
	16. Mallory-Denk bodies: 0 =Rare/absent; 1 =Many
	18. Glycogenosis of hepatocytes: 0 =Not present; 1 =Focal, involving less than 50% of the hepatocytes; 2 =Diffuse,
	involving greater than or equal to 50% of the hepatocytes
	19. Masson's trichrome stain
	a. Fibrosis stage: 0=None → GOTO Item 20; 1a=Mild, zone 3 perisinusoidal (requires trichrome);
	1b =Moderate, zone 3, perisinusoidal (<i>does not require trichrome</i>); 1c =Portal/periportal only;
	2=Zone 3 and periportal, any combination; 3=Bridging; 4=Cirrhosis
	b. Perisinusoidal fibrosis grade: 0=No perisinusoidal fibrosis present; 1=Perisinusoidal fibrosis present that
	requires a Masson stain to identify; 2=Perisinusoidal fibrosis present that is visible on the H&E stain
	c. Predominant location of fibrosis: 0=More predominance around or between portal areas; 1=No portal or
	central predominance; 2=More predominance around/between central veins
	20. Iron stain
	a. Hepatocellular iron grade: 0=Absent or barely discernible, 40x → GOTO item 20c;
	1=Barely discernable granules, 20x; 2=Discrete granules resolved, 10x; 3=Discrete granules resolved, 4x;
	4=Masses visible by naked eye
	b. Hepatocellular iron distribution: 0=Periportal; 1=Periportal and midzonal; 2=Panacinar; 3=Zone 3 or azonal c. Nonhepatocellular iron grade: 0=None → GOTO item 21; 1=Mild; 2=More than mild
	d. Nonhepatocellular iron distribution: 0 =Large vessel endothelium only; 1 =Portal/fibrosis bands only, but
	more than just in large vessel endothelium; 2=Intraparenchymal only; 3=Both portal and intraparenchymal
	21. Is this steatohepatitis? 99 =Not NAFLD; 0 =NAFLD, not NASH; 1a =Suspicious/borderline/indeterminate: Zone
	3 pattern; 1b =Suspicious/borderline/indeterminate: Zone 1, periportal pattern; 2 =Yes, definite
	25. Other comments:

14-Day Blood Pressure Log

Instructions:

- Measure blood pressure every day (preferably each morning) for 14 days.
- Record blood pressure daily in the table below and include the date and time.
- Record the top number (systolic or SBP) and the bottom number (diastolic or DBP).
- To the extent possible, record your blood pressure at the same time every day.
- If needed, use the notes column to highlight any unusual activity before you measure blood pressure.
- Before Checking Your Blood Pressure
 - o Make sure that you are comfortable and relaxed.
 - o Obtain blood pressure measurements on your RIGHT arm every day for 14 days.
 - o Roll up the sleeve on your right arm or remove any tight-sleeved clothing.
 - o Rest in a chair next to a table for 5 to 10 minutes without moving or talking. Your right arm should rest comfortably at heart level. Sit up straight with your back against the chair, legs uncrossed with both feet flat on the ground. Rest your forearm on the table with the palm of your hand facing up.

Important:

- If any of your child's blood pressure measurements are less than 90 systolic or less than 60 diastolic, or your child has symptoms such as dizziness, fainting or lightheadedness, call your study doctor's office or the study coordinator (see contact information below). Call 911 if the symptoms are severe.
- It is important to bring your completed Blood Pressure Log to your next clinic visit.

	Date	Time	AM or PM	Blood Pressure Measurements Systolic: top number; Diastolic: bottom number		Notes
				Systolic	Diastolic	
	06/10/18	8:34	AM)/PM	115 mm/Hg	87 mm/Hg	This is a sample line
1.			AM / PM	mm/Hg	mm/Hg	
2.			AM / PM	mm/Hg	mm/Hg	
3.			AM / PM	mm/Hg	mm/Hg	
4.			AM / PM	mm/Hg	mm/Hg	
5.			AM / PM	mm/Hg	mm/Hg	
6.			AM / PM	mm/Hg	mm/Hg	
7.			AM / PM	mm/Hg	mm/Hg	
8.			AM / PM	mm/Hg	mm/Hg	
9.			AM / PM	mm/Hg	mm/Hg	
10.			AM / PM	mm/Hg	mm/Hg	
11.			AM / PM	mm/Hg	mm/Hg	
12.			AM / PM	mm/Hg	mm/Hg	
13.			AM / PM	mm/Hg	mm/Hg	
14.			AM / PM	mm/Hg	mm/Hg	

1.4		AM / PM	11111/11g	11111/11g	_
14.		AIVI / PIVI	mm/Hg	mm/Hg	_
TO BE COM	PLETED BY CLINIC STA	NFF:			
Study docto	or name (print):		Tel	ephone#:	
Study Coor	dinator name (print):				

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 and key this form whenever the clinical center is informed of a patient's death using as much information about the circumstances of death as possible. Fax a copy of the Death Report (DR) form, including the narrative, and the death certificate (if obtained) to the DCC at (410) 955-0932; Attention: Pat Belt. **Also, complete an Adverse Event (AE) form** and follow the instructions to report a patient's death in STOP-NAFLD.

A. Center, patient, and	visit identifica	tion	9. Source of death report (<i>check all that apply</i>):			
1. Center ID:			a. Patient's family:	(1)	
To Conter 15.			b. Friend:	(1)	
2. Patient ID:			c. Other caregiver:	(1)	
3. Patient code:			d. Health care provider or NASH CRN staff:	(1)	
			e. Newspaper:	(1)	
4. Date form is initiated	l (date of notice	e):	f. Funeral parlor/home:	(1)	
	mon	year	g. Medical record:	(1)	
day	mon	year	h. Medical examiner:	(1)	
5. Visit code:	_n		i. Coroner:	(1)	
			j. National Death Index (NDI):	(1)	
6. Form & revision:		<u> </u>	k. Social Security Death Master File (SSDMF):	(1)	
7. Study:	STOP-NA	AFLD <u>9</u>	l. Other (specify):	(1)	
B. Death information			other source			
8. Date of death:			other source			
day	mon	year				
			10. Place and location of death			
			a. Place of death (check only one):	,	,	
			Hospital	(1)	
			Hospice	(2)	
			Home	(3)	
			Nursing home	(4)	
			Other (specify):	(₅)	
			Unknown	(₆)	
			b. Location of death:		J.	
			city/state/country			

11. Has a death certificate been obtained:

	$\binom{\mathrm{Yes}}{1}$	$\binom{\text{No}}{2}$
If no, please obtain or ex	eplain why not:	

12. Underlying cause of death (Study Physician: use whatever knowledge you have to best characterize the primary cause of death); (CHECK ONLY ONE):

Coronary heart disease	(01)
Cardiovascular disease	13. (₀₂)
Liver disease	14. (₀₃)
Malignancy (cancer)	15. (₀₄)
Gastrointestinal (GI) disease	16. (₀₅)
Pulmonary (lung) disease	17. (₀₆)
Pneumonia	18. (₀₇)
Complication of diabetes	19. (₀₈)
Accident	19. (₀₉)
Suicide	19. (₁₀)
Homicide	19. (₁₁)
Kidney disease or renal failure	19. (₁₂)
Sepsis, staph or other infection	19. (₁₃)
Multi-organ failure	19. (₁₄)
Other (specify):	19. (₁₅)
	19.
Unknown	(₁₆)

Patient ID#:		

13. CAUSE OF DEATH: Coronary heart disease (CHD) subclassification (check only one):

Defined as:	 myocardial infarction (MI) or heart attack Death within 28 days of hospital admission, OR Postmortem findings consistent with MI within 28 days of hospital admission, OR Documented definite or probable MI in previous 28 days if death occurred out of hospital and no evidence of a noncoronary cause of death, OR Autopsy evidence of recent coronary occlusion or MI < 28 days old. 	(1)
Probable fata	MI	(2)
Defined as:	 Death within 28 days of hospital admission in cases defined in probable MI cases, OR Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or not diagnostic). 	`	2,
Definite fatal	CHD	(3)
Defined as:	 A history of CHD and/or documented cardiac pain within 72 hours before death and no evidence of a noncoronary cause of death, OR Autopsy evidence of chronic CHD, including coronary atherosclerosis and myocardial scarring. 		3/
Go to	19.		
CAUSE OF DEA	TH: Cardiovascular (CVD) disease subclassification (check only one): eart failure (CHF)	(1)
CAUSE OF DEA	TH: Cardiovascular (CVD) disease subclassification (check only one):	(1)
CAUSE OF DEA	ATH: Cardiovascular (CVD) disease subclassification (check only one): eart failure (CHF) Death due to clinical, radiologic or postmortem evidence of CHF without clinical or idence of an acute ischemic event (cardiogenic shock included).		
CAUSE OF DEA Congestive he Defined as: It postmortem ev Documented	ATH: Cardiovascular (CVD) disease subclassification (check only one): eart failure (CHF) Death due to clinical, radiologic or postmortem evidence of CHF without clinical or idence of an acute ischemic event (cardiogenic shock included).		1)
CAUSE OF DEA Congestive he Defined as: I postmortem ev Documented Defined as: I	ATH: Cardiovascular (CVD) disease subclassification (check only one): eart failure (CHF) Death due to clinical, radiologic or postmortem evidence of CHF without clinical or idence of an acute ischemic event (cardiogenic shock included). earthythmia Death due to brady- or tachy- arrhythmias not associated with an acute ischemic event.	(2)
CAUSE OF DEA Congestive he Defined as: I postmortem ev Documented Defined as: I Cerebrovascu	ATH: Cardiovascular (CVD) disease subclassification (check only one): Peart failure (CHF) Death due to clinical, radiologic or postmortem evidence of CHF without clinical or idence of an acute ischemic event (cardiogenic shock included). Pearth due to brady- or tachy- arrhythmias not associated with an acute ischemic event. Place (stroke) Death due to stroke occurring within 7 days of signs and symptoms of stroke or during	(
CAUSE OF DEA Congestive he Defined as: It postmortem ev Documented Defined as: It Cerebrovascu Defined as: admission for se	ATH: Cardiovascular (CVD) disease subclassification (check only one): Peart failure (CHF) Death due to clinical, radiologic or postmortem evidence of CHF without clinical or idence of an acute ischemic event (cardiogenic shock included). Pearth due to brady- or tachy- arrhythmias not associated with an acute ischemic event. Pleath due to stroke occurring within 7 days of signs and symptoms of stroke or during stroke.	(₂)
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Go to 19.

Nonalcoholic fatty liver disease (NAFLD) (1) Acute respiratory failure (2) Acute liver failure (3) Other (specify): (2)		CAUSE OF DEATH: Liver disease subclassification (<i>check only one</i>):		18. CAUSE OF DEATH: Pulmonary (lung) subclassification (<i>check only one</i>):		
(NAFLD) Chronic hepatitis C Acute liver failure (3) Other (specify): 19. 19. 19. Contributing causes of death (check all that apply): a. Coronary heart disease (CHD) (specify): (4) 19. Contributing causes of death (check all that apply): a. Coronary heart disease (CHD) (specify): (5) Breast cancer (6) Endometrial/Uterine cancer (7) Endometrial/Uterine cancer (8) Endometrial/Uterine cancer (9) Endometrial/Uterine cancer (10) Endometrial/U		Nonalcoholic fatty liver disease		•	(,)
Chronic hepatitis C Acute liver failure Other (specify): 19.			(1)		(
Acute liver failure Other (specify): (a) 19.		Chronic hepatitis C	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$		(
Other (specify): 19. 19. Contributing causes of death (check all that apply): 10. CAUSE OF DEATH: Malignancy (cancer) subclassification (check only one): 11. Breast cancer		Acute liver failure	$\begin{pmatrix} & & \\ & & \end{pmatrix}$		(.)
(check all that apply): 16. CAUSE OF DEATH: Malignancy (cancer) subclassification (check only one): Breast cancer Colon cancer Colon cancer Eadometrial/Uterine cancer Esophageal cancer Hepatocellular carcinoma (HCC)* Pancreatic cancer Other known cancer or malignant tumor (specify): Unknown cancer site Unknown cancer site Colortadium difficile colitis Diverticular disease Clostridium difficile colitis Castrojemal) Vascular disorders of the intestine Other (specify): (a) (check all that apply): a. Coronary heart disease (CHD) (specify): (b) Corongetive heart failure (CHF): (c) d. Documented arrhythmia, not associated with MI: (e) Other cardiovascular disease (specify): (c) d. Documented arrhythmia, not associated with MI: (e) Other cardiovascular disease (specify): (d) Postate cancer (e) (eheck all that apply): a. Coronary heart disease (stroke): (e) c. Congestive heart failure (CHF): (e) d. Documented arrhythmia, not associated with MI: (e) Other cardiovascular disease (specify): (e) The bloowment of the intestive (e) (f) (h) Liver disease (specify): (h) Liver disease (specify): (h) Liver disease (specify): (h) Liver disease (specify): (h) Cother malignancy (cancer) (specify): (h) Cother cardiovascular disease (stroke): (h) Cother cardiovascular disease (stroke): (h) Cother cardiovascular disease (specify): (h) Cother cardiovascular d		Other (specify):	(4)		`	4 <i>/</i>
(cancer) subclassification (check only one): Breast cancer Colon cancer Colon cancer Endometrial/Uterine cancer Esophageal cancer Hepatocellular carcinoma (HCC)* **Complete and key the HC form. Ovarian cancer Pancreatic cancer Pancreatic cancer Postate cancer Other known cancer or malignant tumor (specify): Unknown cancer site Unknown cancer site Clostridium difficite colitis Diverticular disease Clostridium difficite colitis Diverticular disease Clostridium difficite colitis Diverticular disease (1) Clostridium difficite colitis Postate (specify): (2) Intestinal obstruction Vascular disorders of the intestine (3) Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine (4) Vascular disorders of the intestine (5) Other (specify): (10) Diverticular disease (1) Clostridium difficite colitis (2) Intestinal obstruction (3) Ulcer (gastric, duodenal, peptic, gastrojejunal) (4) Vascular disorders of the intestine (5) Other (specify): (6) M. Cerebrovascular disease (stroke): (7) d. Documented arrhythmia, not associated with MI: e. Other cardiovascular disease (specify): (8) Diabetes Type 1: (9) (1) 10) 11. Hepatocellular (liver) carcinoma (HCC)* (HCC)*: ** Complete and key the HC form. J. Other malignancy (cancer) (specify): (1) k. Gastrointestinal (GI) disease (specify): (1) L. Pulmonary (lung) disease (specify): (2) In. Ridney disease: (3) O. Sepsis, staph or other infection: (4) D. Other (specify): (5) O. Sepsis, staph or other infection: (6) O. Sepsis, staph or other infection: (7) P. Other (specify): (8)	16		19.	(check all that apply):	. (.)
Colon cancer (10.	(cancer) subclassification (check only o	ne):	ar coronary near enough (e112) (speedy)).		1/
Endometrial/Uterine cancer (Breast cancer	(01)	-		
Esophageal cancer Hepatocellular carcinoma (HCC)* (os) * Complete and key the HC form. Ovarian cancer (os) Pancreatic cancer (os) Rectal cancer (os) Rectal cancer or malignant tumor (specify): Unknown cancer site (1) Intestinal obstruction (2) Unter (gastric, duodenal, peptic, gastrojejunal) (3) Vascular disorders of the intestine (2) Other (specify): (3) Intestinal obstruction (3) Unknown cancer (specify): (4) Intestinal obstruction (3) Unknown cancer (1) Intestinal obstruction (1) Vascular disorders of the intestine (2) Other (specify): (3) Intestinal obstruction (1) Naccular disorders of the intestine (2) Other (specify): (3) Intestinal obstruction (1) Intestinal obstr		Colon cancer	(02)	b. Cerebrovascular disease (stroke):	(1)
Hepatocellular carcinoma (HCC)* * Complete and key the HC form. Ovarian cancer Pancreatic cancer Prostate cancer Prostate cancer Other known cancer or malignant tumor (specify): Unknown cancer site Unknown cancer site Unknown cancer site (1) Unknown cancer site (1) Unknown cancer site (1) Unknown cancer of DEATH: Gastrointestinal subclassification (check only one): Diverticular disease (1) Clostridium difficile colitis Ulcer (gastric, duodenal, peptic, gastrojejimal) Vascular disorders of the intestine (3) Ulcer (gastric, duodenal, peptic, gastrojejimal) Vascular disorders of the intestine (5) Other (specify): (1) associated with MI: (1) (2) (3) (4) (4) (5) (6) (7) (7) (8) 1. Hepatocellular (liver) carcinoma (HCC)*: * Complete and key the HC form. (9) (1) * Complete and key the HC form. (2) * Complete and key the HC form. (3) * Ulcer (gastric, duodenal, peptic, gastrojejimal) Vascular disease (specify): (4) * Diabetes Type 1: (5) * Complete and key the HC form. (6) * Complete and key the HC form. (7) * Complete and key the HC form. (8) * Complete and key the HC form. (9) * Complete and key the HC form. (1) * Complete and key the HC form. (9) * Complete and key the HC form. (1) * Complete and key the H		Endometrial/Uterine cancer	(03)	c. Congestive heart failure (CHF):	(1)
*Complete and key the HC form. Ovarian cancer Pancreatic cancer Prostate cancer Rectal cancer Other known cancer or malignant tumor (specify): Unknown cancer site (11) Unknown cancer site (12) Unknown cancer site (13) Course of DEATH: Gastrointestinal subclassification (check only one): Diverticular disease (1) Clostridium difficile colitis (2) Intestinal obstruction (3) Ulcer (gastrio_duodenal, peptic, gastrojejunal) Vascular disorders of the intestine (5) Other (specify): (1) Pulmonary (lung) disease (specify): (1) Pulmonary (lung) disease (specify): (1) Pulmonary (lung) disease (specify): (2) M. Liver disease (specify): (3) (4) K. Gastrointestinal (GI) disease (specify): (4) Pulmonary (lung) disease (specify): (5) M. Pulmonary (lung) disease (specify): (6) M. Pulmonary (lung) disease (specify): (7) Pother (specify): (8)		Esophageal cancer	(04)	d. Documented arrhythmia, not		-
Ovarian cancer Pancreatic cancer Pancreatic cancer Rectal cancer Rectal cancer Other known cancer or malignant tumor (specify): Unknown cancer site (1) Unknown cancer site (1) Unknown cancer site (1) CAUSE OF DEATH: Gastrointestinal subclassification (check only one): Diverticular disease (1) Clostridium difficile colitis (2) Intestinal obstruction (3) Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine (5) Other (specify): (4) Vascular disorders of the intestine (5) Other (specify): (4) Pulmonary (lung) disease (specify): (1) (2) In Pulmonary (lung) disease (specify): (3) (4) Pulmonary (lung) disease (specify): (4) N. Kidney disease: (5) O. Sepsis, staph or other infection: (6) Q. Unknown: (7)		Hepatocellular carcinoma (HCC)*	(05)	associated with MI:	(1)
Pancreatic cancer Prostate cancer Rectal cancer Rectal cancer Other known cancer or malignant tumor (specify): Unknown cancer site Unknown cancer site (1) IP. IP. IP. IP. IP. IP. IP. IP		• •	()	e. Other cardiovascular disease (specify):	(1)
Prostate cancer Rectal cancer Rectal cancer Other known cancer or malignant tumor (specify): Unknown cancer site Unknown cancer site (10) Unknown cancer site (11) Intestinal obstruction Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine Other (specify): (10) Intestinal obstruction Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine Other (specify): (10) Intestinal obstruction (10) Intestinal (GI) disease (specify): (11) Intestinal (GI) disease (specify): (12) Intestinal (GI) disease (specify): (13) Intestinal (GI) disease (specify): (14) Intestinal (GI) disease (specify): (15) Intestinal (GI) disease (specify): (15) Intestinal (GI) disease (specify): (15) Intestinal (GI) disease (specify): (16) Intestinal (GI) disease (specify): (17) Intestinal (GI) disease (specify): (18) Intestinal (GI) disease (specify): (19) Intestinal (GI) disease (specify): (19) Intestinal (GI) disease (specify): (10) Intestinal (GI) disease (specify): (10) Intestinal (G						
Rectal cancer Other known cancer or malignant tumor (specify): Unknown cancer site (10) Unknown cancer site (11) Unknown cancer site (11) Unknown cancer site (11) Intestinal obstruction Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine Other (specify): (10) Intestinal obstruction (10) Vascular disorders of the intestine (10) Unknown cancer site (11) Intestinal obstruction (12) Intestinal obstruction (13) Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine (15) Other (specify): (16) Intestinal (GI) disease (specify): (17) Intestinal (GI) disease (specify): (18) Intestinal (GI) disease (specify): (18) Intestinal (GI) disease (specify): (19) Intestinal (GI) disease (specify): (10) Intestinal (GI) disease (specify): (10) Intestinal (GI) disease (specify): (10) Intestinal (GI) disease (specify): (11) Intestinal (GI) disease (specify): (12) Intestinal (GI) disease (specify): (13) Intestinal (GI) disease (specify): (14) Intestinal (GI) disease (specify): (15) Intestinal (GI) disease (specify): (15) Intestinal (GI) disease (specify): (16) Intestinal (GI) disease (specify): (17) Intestinal (GI) disease (specify): (18) Intestinal (GI) disease (specify): (19) Intestinal (GI) disease (specify): (19) Intestinal (GI) disease (specify): (10) Intestinal (GI) disease (specify):			(₀₇)			
Other known cancer or malignant tumor (specify): Unknown cancer site (1) Unknown cancer site (1) ID. i. Hepatocellular (liver) carcinoma (HCC)*: * Complete and key the HC form. j. Other malignancy (cancer) (specify): (1) k. Gastrointestinal (GI) disease (specify): Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine Other (specify): (2) In Pulmonary (lung) disease (specify): (3) I. Pulmonary (lung) disease (specify): (4) I. Pulmonary (lung) disease (specify): (5) Other (specify): (6) In. Kidney disease: (7) O. Sepsis, staph or other infection: (1) Q. Unknown: (4) Q. Unknown: (5)			(08)	f. Diabetes Type 1:	(1)
Unknown cancer site (g. Diabetes Type 2:	(1)
17. CAUSE OF DEATH: Gastrointestinal subclassification (check only one): Diverticular disease				h. Liver disease (specify):	(1)
Subclassification (check only one): Diverticular disease (1) Clostridium difficile colitis (2) Intestinal obstruction (3) Ulcer (gastric, duodenal, peptic, gastrojejunal) (4) Vascular disorders of the intestine (5) Other (specify): (6) m. Pneumonia: (1) n. Kidney disease: (1) n. Kidney disease: (1) p. Other (specify): (1)		_	(₁₁)	(HCC)*:	(1)
Clostridium difficile colitis Intestinal obstruction Ulcer (gastric, duodenal, peptic, gastrojejunal) Vascular disorders of the intestine Other (specify): 1. Pulmonary (lung) disease (specify): m. Pneumonia: n. Kidney disease: 1. Pulmonary (lung) disease (specify): 1. Pulmonar				j. Other malignancy (cancer) (specify):	(1)
gastrojejunal) (4) 1. Pulmonary (lung) disease (specify): (1) Vascular disorders of the intestine Other (specify): (5) (6) m. Pneumonia: (1) n. Kidney disease: (1) o. Sepsis, staph or other infection: (1) p. Other (specify): (1) q. Unknown: (1)		Clostridium difficile colitis Intestinal obstruction	(₂)	k. Gastrointestinal (GI) disease (specify):	(1)
Other (specify): M. Pneumonia:		gastrojejunal)	(4)	l. Pulmonary (lung) disease (specify):	(1)
m. Pneumonia: (1) n. Kidney disease: (1) o. Sepsis, staph or other infection: (1) p. Other (specify): (1) q. Unknown: (1)			/			
n. Kidney disease: o. Sepsis, staph or other infection: p. Other (specify): q. Unknown: (1)		Other (specify):	(₆)		,	`
o. Sepsis, staph or other infection: p. Other (specify): q. Unknown: (1)					(1)
p. Other (specify): q. Unknown: (1)			ı	-	(1)
q. Unknown: (1)			19.		(1)
				p. Other (<i>specify</i>):	(1)
				q. Unknown:	(
				_	(1)

20.	Was	this	a	procedure-related	death
-----	-----	------	---	-------------------	-------

Y	es	No	
(1)	(2)
		22.	

21. Type of procedure-related death *(check only one):*

Cardiac death: Cardiovascular-related procedure

(Defined as death after invasive cardiovascular intervention. Death within 28 days of cardiovascular surgery or within 7 days of cardiac cath, arrhythmia ablation, angioplasty, atherectomy, stent deployment, or other invasive coronary vascular intervention.):

(`
(1)

Cardiac death: Noncardiovascular procedure

(Defined as cardiac death after noncardiovascular intervention which occurs within 28 days of surgery or other invasive procedure.):

	(2)
Non-cardiac death	(3)
Unknown	(4)

22. Was an autopsy performed (*check only one*):

Yes	(1)
No	(2)
Unknown	((ر

23. Documentation available for future

g. Coroner's report:

formal death adjudication (check all that apply):

a. Medical records documentation:	(1/
b. Report of autopsy findings:	(1/
c. Death certificate:	(1/
d. ER record:	(1/
e. EMS report:	(1/
f. Informant interview:	(1/

h. Other (specify):	(1)	

24. Include a narrative from the Study Physician summarizing the event of death and comorbidities on **page 6** and Fax a copy to the DCC ((410) 955-0932; Attention Pat Belt).

Narrative is included	(1)
Narrative is not included	(2)
If not, please explain why not:		

C. Administrative information

25. Study I	Physician l	PIN:		

26. Study Physician signature:	

29. Date form reviewed:

in ieviewea.		
day	mon	year

Narrative -	do not key:		

FH - Follow-up Medical History

Purpose: To collect follow-up medical history information about the patient.

When: Visits f04, f12, f24, and f36.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient or patient's parent or guardian.

Instructions: Collect information by interview and chart review.

Α.	Center.	visit.	and	natient	identification
л.	Center,	VISIL,	anu	pauciii	luciillication

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

day	mon	year

- **5.** Visit code:
- **6.** Form & revision: __f__h__1__
- 7. Study: STOP-NAFLD 9

B. Interval identification

8. Date of last Follow-up Medical History form (*if this is visit f04, then date of s*):

_		_
day	mon	year

- **9.** Visit code of last Follow-up Medical History form (*if this is visit f04, then s*):
- **10.** Has the participant had a liver biopsy

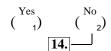


* Complete the Liver Biopsy Materials Documentation (SD) form

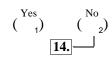
C. Use of effective birth control

since the last visit:

11. Is the patient female:



12. Has menarche occurred:



13. If sexually active, is the patient using two effective birth control methods:

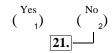
Yes	(1
	/ .1.	

No
* Remind patient to use two forms of birth control.

Not sexually active (3)

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

14. Is the patient age 12 or older:



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

Never	(0
	18.
Monthly or less	(1)
Two to four times a month	(2)
Two to three times a week	(3)
Four or more times a week	(,)

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

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

17. 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	(.)

E. Tobacco cigarette smoking

18. Since the last visit, have you smoked tobacco cigarettes regularly ("No" means smoked less than 1 day per week on average):

Yes (No (2) 21.

19. On average, how many days per week have you smoked cigarettes:

days

20. On the days that you smoked, about how many cigarettes did you smoke per day:

cigarettes per day

F. Recent medical history

21. Has the patient been diagnosed with any of the following since the last visit (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. Hepatitis B:
- **d.** Hepatitis C: (₁) **e.** Autoimmune hepatitis: (₁)
- **f.** Autoimmune cholestatic liver disorder
- (PBC or PSC): (₁)
 g. Wilson's disease: (₁)
- h. Alpha-1-antitrypsin (A1AT)
- deficiency: (₁)
- i. Hemochromatosis or iron overload: (1)
 j. Drug induced liver disease: (1)
- k. Ascites:
- **l.** Gilbert's syndrome: (₁)
- **m.** Esophageal or gastric varices on endoscopy: (, ,)
- **n.** Bleeding from varices: (,)
- o. Gastrointestinal ulcers or other gastrointestinal bleeding:
- **p.** Biliary diversion: (1)
- **q.** Metabolic acidosis: (1)
- **r.** Edema: (₁)
- s. Hepatic encephalopathy: (1)
- **t.** Any other chronic liver disease: (1)
- **u.** Short bowel syndrome:
- v. Hemophilia (bleeding disorder):
- w. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus:
- x. Endocrine disease (hormonal abnormality): (1)
- **y.** Asthma: (1)
- **z.** Hepatocellular carcinoma:
- **aa.** Other malignancy (cancer): **ab.** Human immunodeficiency virus
- (HIV):
- **ac.** Peripheral neuropathy:
- **ad.** Active seizure disorder or epilepsy: $\begin{pmatrix} 1 \end{pmatrix}$
- **ae.** Drug allergies: (

	af. Hypothyroidism:	(1)	G. Drugs historically associated with NAFLD	1	
	ag. Stage 2 hypertension:	(1)	24. Since the last visit, has the patient used		
	ah. Hypotension or orthostatic	,	,	any of the following:		
	hypotension	(1)	Yes	(N	/ o/
	ai. Cerebrovascular disease:	(1)	(1)	1	2 <i>)</i>
	aj. Hyperlipidemia (high cholesterol, high triglycerides):	(1)	(If yes, check all that apply)	1	_
	ak. Pancreatitis:	(1)	a. Amiodarone (Pacerone):	(1)
	al. Cholelithiasis:	(1)	b. Demeclocycline (Declomycin):	(1)
	am. Coronary artery disease:	(1)	c. Divalproex (Depakote):	(1)
	an. Elevated uric acid such as gout:	(1)	d. Doxycycline (Monodox):	(1)
	ao. Kidney disease:	(1)	e. Isonicotinylhydrazine (INH, Isoniazid):	(1)
	ap. Polycystic ovary syndrome:	(1)	f. Isotretinoin (Accutane):	(1)
	aq. Sleep apnea:	(1)	g. Methotrexate (Rheumatrex):	(1)
	ar. Dermatologic disorders:	(1)	h. Minocycline (Dynacin, Minocin):	(1)
	as. Myopathy:	(1)	i. Oxytetracycline (Terramycin):	(1)
	at. Myositis:	(1)	j. Tetracycline (Achromycin):	(1)
	au. Major depression:	(1)	k. Valproate sodium (Depacon):	(1)
	av. Schizophrenia:	(1)	l. Valproic acid (Depakene):	(1)
	aw. Bipolar disorder:	(1)	m. Other known hepatotoxin (specify):	(1)
	ax. Obsessive compulsive disorder:	(1)			
	ay. Severe anxiety or personality disorder:	(1)	25. Since the last visit, has the patient taken		
	az. Substance abuse:	(1)	any systemic glucocorticoids: Yes	N	Jo.
	ba. None of the above:	(1)	$\binom{100}{1}$	(2)
22.	Since the last visit, has the patient had			(If yes, check all that apply)		J
	bariatric surgery (check all that apply)			a. Betamethasone sodium (Celestone):	(1)
	a. Stapling or banding of the stomach:	(1)	b. Cortisol:	(1)
	b. Jejunoileal (or other intestinal) bypass:	()	c. Cortisone:	(1)
	c. Biliopancreatic diversion:	(1)	d. Dexamethasone (Decadron):	(1)
	d. Other bariatric surgery (<i>specify</i>):	(1) 1)	e. Hydrocortisone (Hydrocortone):	(1)
	u. Other barratic surgery (specify).	(1)	f. Methylprednisolone (Solu-Medrol):	(1)
	e. None of the above:			g. Prednisolone (Prelone):	(1)
	e. None of the above.	(1)	h. Prednisone:	(1)
23.	Is the patient currently undergoing evaluation for bariatric surgery:			i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort):	(1)
	Yes	(o/	j. Other, (specify):	(1)

26. Since the last visit, has the patient taken any anabolic steroids or tamoxifen:

g. Oxymetholone (Anadrol):

h. Stanzolol (Winstrol):

k. Other, (specify):

i. Tamoxifen (Nolvadex):

j. Testosterone (Depo-Testosterone):

(Ye (If yes, check all that apply)	es 1) (27.	No 2)
a. Boldenone undecylenate (Equipo	oise): (1)
b. Fluoxymesterone (Android-F, Halotestin):	(1)
e. Methandrostenolone (Dianabol):	(1)
d. Methyltestosterone (Android):	(1)
e. Nandrolone (Deca-Durabolin, Durabolin, Hybolin Decanoate, Kabolin):	(1)
6. Oxandrolone (Oxandrin):	(1)

H. Use of antidiabetic drugs

27. Since the last visit, has the patient used any antidiabetic medications:

b. Acetohexamide (Dymelor):

	Yes (Yes	(N	No 2)
	2	8.	J
(If yes, check all that apply)			
a. Acarbose (Precose):		(1)

- c. Albiglutide (Tanzeum, Eperzan) (d. Alogliptin (Nesina) (
- e. Bromocriptine mesylate (Cycloset)
- **f.** Canagliflozin (Invokana) (₁) **g.** Chlorpropamide (Diabinese): (₁)
- **h.** Dapagliflozin (Farxiga)
- i. Dulaglutide (Trulicity) (1)
- j. Empagliflozin (Jardiance) (1) k. Exanitide (Byetta, Bydureon) (1)
- I. Gliclazide (Diamicron MC)
- **m.** Glimepiride (Amaryl):
- **n.** Glipizide (Glucotrol, Glucatrol XL): $\begin{pmatrix} 1 \end{pmatrix}$
- **o.** Glipizide/Metformin (Metaglip) (₁) **p.** Glyburide (Micronase, DiaBeta,
- Glynase): (1)
- **q.** Glyburide/Metformin (Glucovance) (₁) **r.** Insulin: (,)
- s. Linagliptin (Tradjenta)
- t. Liraglutide (Victoza)
- **t.** Liraglutide (Victoza) (1) **u.** Lixisenatide (Lyxumia) (1)
- v. Metformin (Glucophage, Glucophage
- XR, Glumetza, Fortamet, Riomet): (
- w. Miglitol (Glycet):
- x. Nateglinide (Starlix):
- **y.** Pioglitazone (Actos): $\binom{1}{1}$
- **z.** Pioglitazone/Glimepiride (Duetact)

1)

1

1)

1)

1)

aa. Pioglitazone/Metformin (ActoPlus Met, ActoPlus Met XR)	(1)	J. Use of
ab. Repaglinide (Prandin):	(1)	29. Sinc
ac. Repaglinide/Metformin (PrandiMet)	(1)	any
ad. Rosiglitazone (Avandia):	(
, , ,		1)	
ae. Rosiglitazone/Glimepiride (Avandryl)	(1)	(70
af. Rosiglitazone/Metformin (Avandamet)	(1)	(If y
ag. Saxagliptin (Onglyza)	(1)	a. A
ah. Saxagliptin/Metformin (Kombiglyze XR)	(1)	b. A
ai. Sitagliptin (Januvia)	(1)	c. C
aj. Sitagliptin/Metformin (Janumet)	(1)	d. C
ak. Tolazamide (Tolinase):	(1)	e. E
al. Tolbutamide (Orinase):	(1)	f. E.
am. Vildagliptin (Galvus, Zomelis)	(1)	g. F
an. Other, (specify):	(1)	(1
			T c:
se of supplements, vitamins, and other dr Since the last visit, has the patient taken any of the following supplements/drugs:	ugs		c. h. F X i. G
Since the last visit, has the patient taken any of the following supplements/drugs: Yes		Vo (i. G j. L
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1)			i. G j. L k. N
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29.		Vo (i. G j. L k. N
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) (If yes, check all that apply)	(^N	No 2) 	i. G j. L k. N n. l
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29. (If yes, check all that apply) a. Betaine (Cystadone):		Vo (i. G j. L. k. N m. l n. P
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29. (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine +	(¹)	No 2)	i. G j. L k. N m. l n. F
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (Yes 1) 29. (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA,	(^N	No 2) 1	i. G j. L. k. N n. 1
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29. (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol):		No 2) 1) 1) 1)	i. G j. L. k. N m. l n. P o. R
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29. (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol): d. S-Adenylmethionine (SAM-e):	(¹)	No 2) 1) 1) 1) 1) 1)	i. G j. L k. N m. 1 n. P o. R p. S q. S
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) 29. (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol): d. S-Adenylmethionine (SAM-e): e. Milk thistle:		No 2) 1) 1) 1) 1) 1) 1) 1)	i. G j. L k. N m. 1 n. P o. R p. S q. S
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (Yes 1) (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol): d. S-Adenylmethionine (SAM-e): e. Milk thistle: f. Probiotics:		No 2) 1) 1) 1) 1) 1) 1) 1) 1)	i. G j. L k. N m. 1 n. P o. R p. S q. S
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (1) (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol): d. S-Adenylmethionine (SAM-e): e. Milk thistle: f. Probiotics: g. Vitamin E:		No 2) 1) 1) 1) 1) 1) 1) 1) 1) 1) 1)	i. G j. L k. N m. 1 n. P o. R p. S q. S
Since the last visit, has the patient taken any of the following supplements/drugs: (Yes (Yes 1) (If yes, check all that apply) a. Betaine (Cystadone): b. Choline + methionine + betaine + adenosine + pyridoxine (Epocler): c. Ursodeoxycholic acid (UDCA, Actigall, URSO, Ursodiol): d. S-Adenylmethionine (SAM-e): e. Milk thistle: f. Probiotics:		No 2) 1) 1) 1) 1) 1) 1) 1) 1) 1)	i. G j. L k. N m. 1 n. P o. R p. S q. S

specify *Note: Patient should not take potassium supplements during the trial.

atins, fibrates, and antiobesity drugs

he last visit, has the patient taken id lowering medications:

Yes			No			
(1)	(2)			
		30. —				

check all that apply)

a. Amlodipine/atorvastatin (Caduet):	(1)
b. Atorvastatin (Lipitor):	(1)
c. Colestipol hydrochloride (Colestid):	(1)
d. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate):	(1)
e. Ezetimibe/atorvastatin (Liptruzet):	(1)
f. Ezetimibe/simvastatin (Vytorin):	(1)
g. Fenofibrate tablets or micronized (Fenoglide, Lipofen, Lofibra tablets, Tricor, Triglade, Antara, Lofibra capsules):	(1)
h. Fluvastatin sodium (Lescol, Lescol XL):	(1)
i. Gemfibrozil (Gen-Fibro, Lopid):	(1)
j. Lovastatin (Altoprev, Mevacor):	(1)
k. Niacin/lovastatin (Advicor):	(1)
l. Nicotinic acid (Niaspan):	(1)
m. Pitavastatin (Livalo):	(1)
n. Pravastatin sodium (Pravachol):	(1)
o. Rosuvastatin (Crestor):	(1)
p. Simvastatin (Zocor):	(1)
q. Sitagliptin/simvastatin (Juvisync):	(1)
r. Other, (specify):	(1)

k. Vitamin D: **l.** Multivitamin:

m. Potassium (any form):

n. Other (specify):

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

Y	es	No
(1)	(2)
		31.

(If yes, check all that apply)

i. Other, (specify):

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

K. Use of other medications

31. Since the last visit, has the patient taken any histamine H2 receptor antagonists, antacids, or other medications:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)
	32.

(If yes, check all that apply)

a. Cimetidine (Tagamet):	(1)
b. Esomeprazole magnesium (Nexium):	(1)
c. Famotidine (Pepcid):	(1)
d. Lansoprazole (Prevacid):	(1)

32. Has the patient taken any pain relieving, non-steroidal anti-inflammatory, or aspirin containing medications in the past 6 months:

(If yes, check all that apply)

a. Acetaminophen (Tylenol):	(1)
b. Aspirin - 81 mg:	(1)
c. Aspirin - 325 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)

^{*}Note: Patient should be cautioned against daily use of NSAIDs during the trial.

33.	Since the last visit, has the patient taken
	any cardiovascular/antihypertensive
	medications:

Yes	No
$(*_1)$	(2)
•	34.
	34.

(If yes, check all that apply)		
a. Aliskiren (Tekturna):	(1)
b. Amlodipine besylate (Norvasc):	(1)
c. Atenolol (Tenormin):	(1)
d. Benazepril (Lotensin):	(1)
e. Bisoprolol (Zebeta):	(1)
f. Candesartan cilexetil (Atacand):	(1)
g. Captopril (Capoten):	(1)
h. Chlorthalidone (Thalitone):	(1)
i. Clonidine (Catapres):	(1)
j. Digoxin (Lanoxin):	(1)
k. Diltiazem (Cardizem):	(1)
l. Doxazosin (Cardura):	(1)
m. Enalapril (Vasotec):	(1)
n. Felodipine (Plendil):	(1)
o. Fosinopril (Monopril):	(1)
p. Furosemide (Lasix):	(1)
q. Hydrochlorothiazide (Esidrix, HydroDIURIL):	(1)
r. Hydrochlorothiazide + triamterene (Dyazide):	(1)
s. Irbesartan (Avapro):	(1)
t. Isadipine (DynaCirc, Prescal):	(1)
u. Lisinopril (Prinivil, Zestril):	(1)

v. Losartan potassium (Cozaar):

w. Losartan potassium with hydrochlorothiazide (Hyzaar):

y. Nifedipine (Adalat, Procardia):

x. Metoprolol (Lopressor):

z. Olmesartan (Benicar):

aa. Pernexiline maleate:	(1)
ab. Prazosin (Minipress):	(1)
ac. Propranolol (Inderal):	(1)
ad. Quinapril (Accupril):	(1)
ae. Ramipril (Altace):	(1)
af. Terazosin (Hytrin):	(1)
ag. Timolol maleate (Blocadren):	(1)
ah. Valsartan (Diovan):	(1)
ai. Verapamil (Calan):	(1)
aj. Other, (specify):	(1)

34. Since the last visit, has the patient taken any antipsychotic or antidepressant medications:

j. Sertraline (Zoloft):

k. Other (specify):

Y	es	No	
(1)	(ر,
,		ا أ	
		35.	

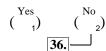
(If yes, check all that apply)		
a. Aripipazole (Abilify):	(1)
b. Buporpion (Wellbutrin):	(1)
c. Clomipramine (Anafranil):	(1)
d. Escitalopram (Lexapro):	(1)
e. Fluoxetine (Prozac):	(1)
f. Fluvoxamine (Luvox):	(1)
g. Lithium (Eskalith, Lithobid):	(1)
h. Quetiapine (Seroquel):	(1)
i. Risperidone (Risperdal):	(1)

1)

1)

^{*}Note: Patient should not start antihypertensive medications during the trial.

35. Has patient taken any of the following medications in the past 6 months:



(If yes, check all that apply)

- **a.** Levonorgestrel (Norplant):
- **b.** Levothyroxine (Levoxyl, Synthroid): (₁)
- **c.** Liothyronine (Cytomel):
- **d.** Oral contraceptives:
- e. Penicillamine (Cuprimine, Depen):
- **f.** Trientine hydrochloride (Syprine): (1)
- **g.** Other, (specify):
- **h.** Other, (specify):
- i. Other, (specify):
- **j.** Other, (specify):
- **k.** Other, (specify):
- L. Administrative information
- **36.** Study Physician PIN:
- **37.** Study Physician signature:
- **38.** Clinical Coordinator PIN:
- **39.** Clinical Coordinator signature:
- ____
- **40.** Date form reviewed:

day	mon	year

HF - Liver Biopsy Histology Findings

 $\textbf{Purpose}: \ Record\ results\ of\ the\ histologic\ evaluation\ of\ slides\ from\ the\ liver\ biopsy\ for\ eligibility.$

When: Visit s.

By whom: Clinical Coordinator after Study Pathologist completed the Histology Worksheet (HW form).

Instructions: The Study Pathologist should complete the Histology Worksheet (HW) using the institution's H & E slide and if available, the institution's Masson's trichrome and iron slides. After completing the HW form, the Study Pathologist should give the worksheet to the Clinical Coordinator who will transcribe the data to the HF form and staple the worksheet to the HF form. If is checked for any item, the patient is not eligible for STOP-NAFLD and the form should not be keyed. If is checked for an item, use caution; if the Study Physician agrees with the diagnosis, the patient is ineligible for STOP-NAFLD and the form should not be keyed. If fewer than 3 unstained slides are available for the biopsy, the institution's H & E and Masson's trichrome slides must be sent to the DCC for central pathology review. If 3 or more unstained slides are available for the biopsy, only the unstained slides need to be sent to the DCC. The Study Pathologist should forward the stained slides (if needed) and up to 10 unstained slides to the Clinical Coordinator for forwarding to the DCC. NOTE: If this biopsy was previously read for DB2, the study pathologist does not need to score the biopsy again. Contact the DCC to obtain the results from the Central Review, if the Central Review has not been done yet, transcribe the data from the existing DB2 HW form to the STOP-NAFLD HF form.

11. Biopsy length:
mm
C. NASH evaluation (use H & E and Masson's trichrome slides only)
19 Steatesia (assume manne a glange and small
12. Steatosis (assume macro, e.g., large and small droplet)
a. Grade: < 5% (0)
5-33% (,)
34-66%
> 66%
b. Location:
Zone 3 $\begin{pmatrix} & & & & & & & & & & & & & & & & & & $
Zone 1 $\begin{pmatrix} 1 \end{pmatrix}$
Azonal (2)
Panacinar (3)
13. Fibrosis stage (Masson's trichrome stain)
0: None (₀)
1a: Zone 3, perisinusoidal (requires trichome) (,)
1b: Zone 3, perisinusoidal (easily seen on H & E) $\left(\begin{array}{c} 2 \end{array}\right)$
1c: Portal/periportal only $\binom{3}{2}$
2: Zone 3 and periportal, any combination (4)
3: Bridging $\begin{pmatrix} & & & \\ & & 5 \end{pmatrix}$
4: Cirrhosis
~~ <u>~</u>

14. Inflammation

a. Amount of lobular inflammation: combines mononuclear, fat granulomas, and pmn foci:

0	(0)
< 2 / 20x mag	(1)
2-4 / 20x mag	(2)

b. Amount of portal, chronic inflammation:

> 4 / 20x mag

None to minimal $\begin{pmatrix} 0 \\ 0 \end{pmatrix}$ Mild $\begin{pmatrix} 0 \\ 1 \end{pmatrix}$

More than mild (

15. Hepatocellular ballooning:

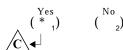
None	(0
Few	(1)
Many	(2)

16. Is steatohepatitis present:

Not NAFLD	Exig)—	0
NAFLD, not NASH	(1)
Suspicious/borderline/indeterminate (2 or 3 on HW form, item 14)	(2)
Yes, definite (4 on HW form, item 14)	(3

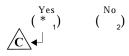
D. Exclusion of other liver disease

17. Is there evidence of primary biliary cirrhosis:



* Caution: Primary biliary cirrhosis is exclusionary

18. Is there evidence of Wilson's disease:



* Caution: Wilson's disease is exclusionary

19. Features of chronic cholestatic liver disease *(check all that apply)*

a. Bile duct loss/infiltration/sclerosis:	(* (*	
	<u>/C</u> \←	
b. Florid duct lesions:	(1)
c. Cholate stasis:	(.)

d. Copper deposition:

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

(1)

f. None:

* Caution: Bile duct obstruction and primary sclerosing cholangitis are exclusionary

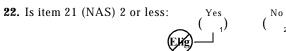
- **20.** Features of other forms of chronic liver disease *(check all that apply)*
 - **a.** Vascular lesions of ALD/B-C/OVD: (,)
 - **b.** Inflammation suggestive of AIH, HCV:
 - c. Pigment suggestive of HH:
 - **d.** Globules suggestive of A1AT: (* ,
 - **e.** Hepatocellular changes suggestive of HBV: (* 1)
 - **f.** Granulomas suggestive of sarcoid, PBC, infection: (* ,
 - **g.** Other (specify):

h.	None:	(1)
		,	1'

^{*} Caution: Exclusionary if the study physician agrees with diagnosis.

E. NAFLD Activity Score

21. NAFLD activity score (NAS) (sum of items 12a, 14a, and 15)	
(1.2.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1	0-8
22 7 11 24 (271.6) 2 1	



F. Other comments

23.	Ot	her	con	nme	nts	:				
	•									

G. Administrative information

- **25.** Study Pathologist signature (Pathologist does not need to sign this form if a signed HW form is attached or if Central Review scoring was used.):
- **26.** Clinical Coordinator PIN: ____ ____
- 27. Clinical Coordinator signature:
- 28. Date form reviewed:
 - day mon year

NASH CRN

HW - Liver Biopsy Histology Worksheet

Purpose: Record results of histologic evaluation of slides from screening liver biopsy.

When: Whenever a biopsy is evaluated by the Study Pathologist for the NASH CRN.

By whom: Study Pathologist at the NASH CRN clinical center (this is not the form used for central reading) and Clinical Coordinator.

Instructions: The Study Pathologist should complete this form using the institution's H & E slide and if available, the institution's Masson's trichrome slide. Details for scoring liver biopsy can be found in the NAFLD Database 2 SOP IV. Upon completion of this form, the Study Pathologist should give the HW form to the Clinical Coordinator. The Clinical Coordinator should transcribe the information on the Liver Biopsy Histology Worksheet (HW) to the Liver Biopsy Histology Findings (HF) form for the study for which the patient is being evaluated; the worksheet should be stapled to the HF form. If the biopsy is being used for more than one NASH CRN study, the biopsy should only be read by the local pathologist once; the worksheet should be copied and attached to both HF forms.

A. Center, patient and visit identification	Masson's trichrome slides only)
1. Center ID:	
2. Patient ID:	10. Steatosis (assume macro, e.g., large and small droplet)
	a. Grade:
3. Patient code:	< 5%
	5-33% (1)
4. Date of reading:	34-66% (2)
	> 66% (3)
day mon year	b. Location:
	Zone 3 $\begin{pmatrix} & & & & & & & & & & & & & & & & & & $
5. Visit code:	Zone 1 $\binom{1}{1}$
1 2	Azonal (₂)
6. Form & revision: _h_ w2_	Panacinar (3)
B. Biopsy information	11. Fibrosis stage (Masson's trichrome stain)
	0: None (₀)
7. Date this biopsy was performed (<i>obtained from surgical pathology report</i>):	1a: Zone 3, perisinusoidal (requires trichome) (1)
day mon year	1b: Zone 3, perisinusoidal (easily seen on H&E) (2)
8. What slides are to be used in this	1c: Portal/periportal only (3)
evaluation (check all that apply)	2: Zone 3 and periportal, any
a. H & E: (₁)	combination (4)
b. Masson's trichrome: (1)	3: Bridging (5)
c. Iron: (₁)	4: Cirrhosis (₆)
9. Biopsy length:	
mm	

12	T., £1	4:
LZ.	Inflam	mation

a. Amount of lobular inflammation:
combines mononuclear, fat
granulomas and pmn foci-

0	(0
< 2 / 20x mag	(1)
2-4 / 20x mag	(2)

> 4 / 20x mag

None to minimal	(ر0
Mild	(1)
More than mild	()

13. Hepatocellular ballooning:

None	(0
Few	(1)
Many	(2)

14. Steatohepatitis diagnosis:

Not NAFLD	(0)
NAFLD, but not NASH	(1)
Suspicious/borderline/indeterminate,		
zone 3 pattern (1A)	(2)
~		

Suspicious/borderline/indeterminate,		
zone 1, periportal pattern (1B)	(3)
Yes, definite steatohepatitis	((ړ

15.	NAFLD activity score (NAS)
	(sum of items 10a, 12a, and 13):

D. Exclusion of other liver disease

16. Is there evidence of primary biliary cirrhosis:

Y	es .	N	О
(1)	(2

0-8

17. Is there evidence of Wilson's disease:

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

18.	Features of chronic cholestatic liver
	disease (check all that apply):

a. Bile duct loss/infiltration/scierosis:	(1
b. Florid duct lesions:	(1
c. Cholate stasis:	(1
d. Copper deposition:	(1

e. Other (specify):	(1/

19	Features of other forms of chronic liver	

19.	reatures of other forms of chronic liver
	disease (check all that apply):

a. Vascular lesions of ALD/B-C/OVD:	(1)
b. Inflammation suggestive of AIH,	(,

HCV:	(1
c. Pigment suggestive of HH:	(1

f. Granulomas suggestive of sarcoid,		
PBC, infection:	(1

1 Be, infection.	(1
g. Other (specify):	(1

h. None:	(1,

E. Other comments

f. None:

20. Other comments:

F. Administrative information

- 21. Study Pathologist PIN:
- **22.** Study Pathologist signature:

STOP-NAFLD

LR - Laboratory Results - Tests Done at Screening and Followup Visits

Purpose: To record archival and current laboratory test results for tests done during both screening and followup. When: Visits s, f04, f12, f24 and f36.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat tests if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Call the DCC if you have any questions about conversions or how to record a value. Attach copies of the laboratory reports to this form. If is checked for any item, then the form should not be keyed.

A. Center, patient, and visit identification	13. White blood cell value	es
1. Center ID:	a. White blood cell count (WBC):	
2. Patient ID:		$\frac{\bullet}{10^3 \text{ cells/} \mu \text{L}} \text{ or } 10^9 \text{ cells/L}$
3. Patient code:	b. Red blood cell cour	at (RBC):
4. Date of visit:		•
	_	mill cells/μL
day mon year	c. Neutrophils:	cells/μL
5. Visit code:		CONS/ µL
6. Form & revision:	d. Lymphocytes:	cells/ µL
7. Study: STOP-NAFLD 9	e. Monocytes:	cells/ μL
B. Hematology		
Required at visits s, f12, f24, and f36.	f. Eosinophils:	cells/ μL
8. Is hemotology required at this visit: (Yes (No 1) 15.	g. Basophils:	cells/ μL
9. Date of blood draw for complete blood count:	14. Platelet count:	
		cells/mm ³
day mon year Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).	If platelets < 100,000 screening, patient is in	$0 \text{ cells/mm}^3 (mm^3 = \mu L) at eligible.$
10. Hemoglobin:		
11. Hematocrit:		
12. Mean corpuscular volume (MCV):		

C. Chemistries

Required at all visits.

15. Date of blood draw for chemistries:

_		_
day	mon	year

Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

16	Sodium
TU.	Souluili

_		_
	mFa/I	

17. Potassium:

•	
mEq/L	

a. Upper limit of normal: __

•	
 mEq/L	-

18. Chloride:

mEq/L

19. Bicarbonate:

•	
 mEq/L	

20. Calcium:

•	
 mg/dL	

21. Blood urea nitrogen (BUN):

mg/dL

22. Creatinine:

(if creatinine > 2.0 mg/dL at screening, patient is ineligible:)

•	
 mg/dL	

a. Upper limit of normal: __

	•	
 mg	/dL	-

23. eGFR:

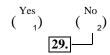
(to calculate eGFR use Bedside IDMS-traceable Schwartz GFR Calculator for Children (https://jhuccs1.us/nash/closed/cped/STOP-NAF LD/STOPNAFLD.htm); enter 75.0 if eGFR is ≥ 75mL/mim/1.73m²; if eGFR <60mL/mim/1.73m² at screening patient is ineligible)

•	
$mL/min/1.73m^2$	

D. GGT, Prothrombin, and INR

Required at visits s, f12, and f24.

24. Are GGT, PT, and INR required at this visit:



25. Date of blood draw for GGT, prothrombin time, and INR:

day	mon	year

Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

26. Gamma glutamyl transferase (GGT):

U/L	

27. Prothrombin time (PT):

	•	
 S	ec	

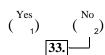
28. International normalized ratio (INR) (if INR > 1.3, patient is ineligible):



E. Uric acid and C-reactive protein

Required at visits s, f12, f24 and f36.

29. Are uric acid and CRP required at this visit:



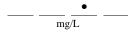
30. Date of blood draw for uric acid and CRP:

dav	mon	vear

Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

 32. C-reactive protein:

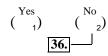
(if CPR results are given in mg/dL, multiply results by 10; if result is <0.5 mg/dL, enter 05.0 and indicate the actual result in a comment):



F. Hemoglobin A1c

Required at visits s, f12, and f24.

33. Is HbA1c required at this visit:

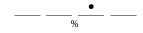


34. Date of blood draw for HbA1c:



Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

35. HbA1c (if HbA1c is > 9.5% at screening; patient is ineligible):



G. Liver panel

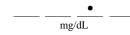
Required at all visits.

36. Date of blood draw for liver panel:



Date must be within the required time window. The ALT measurement must be within 30 days of randomization; other liver panel measurements must be within 60 days of randomization. It is preferred that the entire liver panel be within 30 days. In cases where only the ALT is redrawn, use the date of the ALT measurement in item 36, and include the date of the other liver panel measurements in the general comments. Follow-up blood draws must be within the window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

37. Bilirubin (total):



a. Upper limit of normal:



38. Bilirubin (conjugated or direct*)

(if direct bilirubin > 1.3 mg/dL at screening, patient is ineligible):

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

•	
mg/dL	

39. Aspartate aminotransferase (AST)

U/L	

a. Upper limit of normal:

	II	/T	

40. Alanine aminotransferase (ALT) (if ALT < 50 U/L or ALT > 300 U/L at screening, patient is ineligible)

U/L	

a. Upper limit of normal:

/T .

41. Alkaline phosphatase

U/L	

a. Upper limit of normal:

 U/L	

42. Albumin (if albumin < 3.2 g/dL at screening, patient is ineligible):

•	
g/dL	

43. Total protein:

	•	
_	g/dL	

H. Fasting lipid profile

Required at visits s, f12, and f24.

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

44. Is the lipid profile required at this visit:



45. Was participant fasting for at least 8 hours prior to blood draw:

$$\begin{pmatrix} \text{Yes} & \begin{pmatrix} \text{No} \\ 1 \end{pmatrix} & \begin{pmatrix} \frac{1}{2} \end{pmatrix} \end{pmatrix}$$

*12 hour fasting is preferred, but will accept nonfasting lipid values. 46. Date of blood draw for fasting lipid profile:

year

Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

a. Triglycerides:

mg/dL

b. Total cholesterol:

mg/dL

c. HDL cholesterol level:

d. LDL cholesterol level*:

mg/dL

mg/dL

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

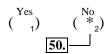
I. Fasting glucose and insulin

Required at visits s, f12, and f24.

47. Are glucose and insulin required at this visit:



48. Was participant fasting for at least 8 hours prior to blood draw:



*Patient must be fasting; 12 hour fasting is preferred. Fasting glucose and insulin must be obtained at visit s.

49. Date of blood draw for fasting glucose and insulin:

> day mon year

Date must be within the required time window; within 60 days of randomization or in the time window for the follow-up visit (check the patients STOP-NAFLD visit time window guide).

a. Glucose: mg/dL

b. Was glucose obtained using plasma or serum:

Plasma Serum

c. Insulin:

d. Was insulin obtained using plasma or serum:

Plasma Serum

J. Pregnancy test

Required at all study visits, if applicable.

50. Is pregnancy test applicable:



51. Date of urine collection (or blood draw):

dav mon year

Date must be the same day as date of visit.

52. Pregnancy test result (if pregnancy test is positive at screening visit, patient is ineligible):

Positive

Negative

- K. Eligibility check
- **53.** Is this the screening visit:

54. Was the patient found to be ineligible based on platelet count (item 14), creatinine (item 22), eGFR (item 23), INR (item 28), HbA1c (item 35), direct bilirubin (item 38), ALT (item 40), albumin (item 42), pregnancy test (item 52), or based on missing tests:



L. Administrative information

55. Study Physician PIN:	

56.	Study	Physician	signatu	re:	

58.	Clinical	Coordinator sign	nature:

59. Date form reviewed:

day	mon	year

STOP-NAFLD

LS - Laboratory Results Tests Done Only During Screening

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

When: Visit s.

Administered by: Study Physician 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. If is checked for any item the patient is not eligible for the STOP-NAFLD trial. If is checked for an item and the Study Physician agrees with the diagnosis, the patient is ineligible for STOP-NAFLD.

A. Center, patient, and visit identification		B. Screening etiologic tests	
1. Center ID:		8. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:	
2. Patient ID:			
3. Patient code:		day mon year Repeat if date is greater than 5 years prior to screening.	
4. Date of visit:		a. Hepatitis B surface antigen (HBsAg): Positive	
day	mon year	E Ag .	
5. Visit code:	_S	Negative (2)	
6. Form & revision:	<u>l s l</u>	b. Hepatitis C antibody (anti-HCV) (indicate result as negative if EIA is positive but RIBA is negative):	
7. Study:	STOP-NAFLD 9	Positive (1)	
		Negative (2)	
		c. Hepatitis C virus RNA (HCV RNA):	
		Positive (1)	
		Negative (2)	
		Not available (3)	

C. Autoantibody studies

9. Date of blood draw for autoantibody tests:

day	mon	year
	1 5	. ,

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

10. Anti-nuclear antibody (ANA):

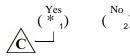
Positive	(* 1)
Negative	(2)
	12.

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

a. Titer (record only the denominator):

	1/
b. Units:	
	mg/dL

11. Is ANA titer greater than 1:80



* Check Liver Biopsy Histology Findings Form for autoimmune liver disease.

12. Date of blood draw for anti-smooth muscle antibody (ASMA):

_		=
day	mon	year

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

13. Anti-smooth muscle antibody (ASMA):

Positive	(*)
Negative	(2
	14.

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

a. Titer (record only the denominator):

	1/
b. Units:	
	mg/dL

14. Date of blood draw for anti-mitochondrial antibody (AMA):

day	mon	year
Repeat if date is gred	ater than 5 year	s prior to
screening.		•

15. Anti-mitochondrial antibody (AMA):

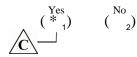
Positive	(*)
Negative	(2
Not available	17. (₃
	17.

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

a. Titer (record only the denominator):

	1/
b. Units:	•
	mg/dL

16. Is AMA titer greater than 1:80



* Check Liver Biopsy Histology Findings Form for primary biliary cirrhosis.

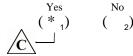
D. Ceruloplasmin

17. Date of blood draw for ceruloplasmin:

 day		vear
Repeat if date is g screening.	reater than 5 year	rs prior to
8. Ceruloplasmin		<u> </u>

a. Lower limit of normal: _____ mg/dL

b. Is ceruloplasmin below the lower limit of normal:



* Check Liver Biopsy Histology Findings Form for Wilson's Disease.

E. Alpha-1 antitrypsin

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

day mon year

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

20. Alpha-1 antitrypsin (A1AT):

mg/dL

a. Lower limit of normal:

21. A1AT phenotype* (check only one):

MM (1)
MS (2)

MZ (3) SZ (4)

ZZ $\begin{pmatrix} 47 \\ 5 \end{pmatrix}$

Other (specify): (

	specify		
Not available		(`

- *If the phenotype result includes numbers, the numbers should be disregarded when reporting the result (e.g., M1M2 should be reported as MM).
- **22.** Is A1AT deficiency the primary cause of this patient's liver disease (*physician assessment*):



F. Iron

23. Date of blood draw for iron overload screening:

day mon year

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

a. Serum iron:

μg/dL

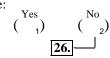
b. Total Iron Binding Capacity: ____ ___

 $\frac{}{\mu g/dL}$

c. Ferritin:

ng/mL

24. Is hepatic iron index available:



25. Hepatic iron index:

• μmol/g/year

G. Other screening blood tests

26. Is thyroid stimulating hormone available within 5 years of screening:



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

day mon year

28. Thyroid stimulating hormone:

•	
<u>μU/mL</u>	

H. Administrative information

74	Study	Physician	DIN:		
47.	Study	1 II y SICIAII	IIII.		

- **30.** Study Physician signature:
- **31.** Clinic Coordinator PIN: ____ ___
- **32.** Clinic Coordinator signature:
- **33.** Date form reviewed:

_		_
day	mon	year

STOP-NAFLD

MV - Missed or Incomplete Visit

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

When: At the close of a visit window for any missed follow-up visit or for any follow-up visit with specific forms not completed. Use visit code f02, f04, f12, f24, or f36.

Respondent: None.

Completed by: Clinical Coordinator.

Instructions: Complete this form when a patient fails to complete a visit or specific visit procedures (resulting in missing forms) within the time window for the visit.

A. Center, patient, and visit identification	10. Steps taken to avoid missing the visit (check all that apply)			
1. Center ID:		a. Telephoned patient:	(1)
		b. Mailed reminder card:	(1)
2. Patient ID:		c. Other (specify):	(1)
3. Patient code:		specify		
4. Date form completed:		14.	<u> </u>	١
day mon	year	D. Missed form information		
5. Visit code:f		11. Check form(s) not completed (check all that apply)		
6. Form & revision:mv	1	a. Blood Processing for Plasma and Serum (BP):	(1)
CEOD NA EL	D 0	b. Follow-up Medical History (FH):	(1)
7. Study: STOP-NAFL	D _9	c. Beverage intake questionnaire (BQ):	(1)
B. Reason for completion of this form		d. Laboratory Results - Tests Done During Screening and Follow-up (LR):	(1)
8. Was the entire visit missed:		e. Physical Examination (PE):	(1)
Yes	No	f. Focused Physical Examination (PF):	(1)
(1)	(2)	g. Parent Report for Teens (13-17) (PQ):	(1)
	1.	h. Pediatric QOL: Parent Report for Child (8-12) (PR):	(1)
C. Missed visit information		i. Pediatric QOL: Child Report (PW):	(1)
9. Reason for missed visit (check all that ap	ply)	j. Pediatric QOL: Teen Report (PY):	(1)
a. Patient was ill:	(1)	k. Study Drug Dispensing and Return (RD):	(1)
b. Patient was temporarily away from area:	(1)	1. Other (specify):	(1)
c. Patient refused to return:	(1)			
d. Patient has permanently moved from the area:	(1)	specify		
e. Unable to contact patient:	(1)	12. Reason form(s) not completed (check all that apply)		
f. Other (specify):	()	a. Patient was ill:	(1)
i. Outer (specify).	(1)	b. Patient/parent refused procedure:	(1)
specify		c. Procedure forgotten:	(1)
specify		d. Other (<i>specify</i>):	(1)

specify

	s made to con	mplete form(s)		
a. Atten	npted to resch	nedule procedure:	(1)
	npted to colle from patien	ect interview data by t/parent:	(1)
	npted to gain ration:	patient/parent	(1)
d. Other	(specify):		(1)
E. Administra	ntive informa	specify tion		
14. Clinical	Coordinator	PIN:		
15. Clinical	Coordinator	signature:		
16. Date for	m reviewed:			
	day	mon	year	

PE - Physical Examination

Purpose: Record	detailed physical exam findings.		
When: Visits s an	nd f24.		
Administered by	: Study Physician and Clinical Coordinate	or.	
Respondent: Pat			
are found in the patient standing weight is <70 metrics be keyed. Metrics and the long measurements you have two pobtained at each of the patient long diastolic bloods.	e STOP-NAFLD SOP, Part I. In brief: Fig and wearing light clothing. Shoes show kg (154 lbs) or >150 kg (330 lbs) at screen asure the waist around the abdomen horizowest part of the costal margin in the mice within 4 in (10.2 cm) of each other. Memeasurements within 4 in (10.2 cm) of each visit. The stage 2 hypertension or if the average of the costal margin in the mice with the costal margin in the mice within 4 in (10.2 cm) of each other. Memeasurements within 4 in (10.2 cm) of each visit.	aist, hip, and blood pressure measurements leight, weight, waist and hips all should be railed be removed for height and weight measuring visit the patient is ineligible and the Patontally at the midpoint between the highest axillary line. Repeat waist measurements assure the hips at the fullest part. Repeat hip ach other. Three blood pressure measurements as screening systolic blood pressure is >140 of the average systolic blood pressure is <90 of for symptoms of hypotension.	measured with the ures. If patient's E form should not t point of the iliac until you have two measurements until nts should be
Center, patient, and	d visit identification	9. Weight (shoes off)	
1. Center ID:		a. 1st measurement:	
2. Patient ID:		b. 2nd measurement:	
3. Patient code:		c. Units:	
4. Visit date:		Pounds	$\begin{pmatrix} & & 1 \end{pmatrix}$
		Kilograms	(2)
5. Visit ID code6. Form & revis	:	10. Waist (standing, at midpoint of iliac crest and lowest part waist measurements until you within 4 in (10.2 cm) of each	t of costal margin; repea u have two measurement
	- — —	a. 1st measurement:	
7. Study::	STOP-NAFLD 9		
		b. 2nd measurement:	
Measurements		c. Units:	
8. Height (shoes	off)	Inches	()
a. 1st mea	surement:	Centimeters	$\begin{pmatrix} & 1 \end{pmatrix}$ $\begin{pmatrix} & 2 \end{pmatrix}$
b. 2nd mea	asurement:	11. Hip (standing, at fullest part measurements until you have within 4 in (10.2 cm) of each	of the hips; repeat hip two measurements
c. Units:		a. 1st measurement:	
Inches	(1)		
Centime	eters (₂)	b. 2nd measurement:	
		c. Units:	•

A.

В.

Inches Centimeters

- **12.** Arm circumference (repeat mid-upper arm circumference until you have two within 1.5 in (3.8 cm) of each other)
 - **a.** Mid-upper arm circumference, 1st measurement:

	•	
arm circu	ımferen	ce

b. 2nd measurement:

		•	
		—— mferen	
arm (circili	mterena	e.

c. Units for arm circumference:

Inches	(1.
Centimeters	(2.

13. Temperature (oral)

a.	Degrees:	 	 	
	0 1			

- b. Scale:
 Fahrenheit: (1)
 Centigrade: (2)
- **14.** Blood pressure
 - a. Systolic, 1st reading: _____ mmHg ____
 - **b.** Diastolic, 1st reading: _____ mmHg ____
 - c. Systolic, 2nd reading: ____ mmHg ___
 - **d.** Diastolic, 2nd reading: _____ mmHg ____
 - e. Systolic, 3rd reading: ____ mmHg
 - **f.** Diastolic, 3rd reading: _____ mmHg ____
- **16.** Respiratory rate: breaths/minute

C. Examination findings

17. Skin:



18. Acanthosis nigricans (check only one):

Present (clearly present on close	
inspection, not visible to casual observer,	
* * \	/

Absent (not detectable on close inspection) (

nspection, not visible to casual observer,		
extent not measurable)	(1)
M:11 //::4-14-1		

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

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

19. Other skin abnormality (check all that apply)

a.	Jaundice:	(1)
b.	Palmar erythema:	(1)
c.	Spider angiomata:	(1)

- c. Spider angiomata: (1)
 d. Striae: (1)
- **e.** Skin lesions: (1) **f.** Other (specify): (1)
- g. None of the above:
- 20. Head, eyes, ears, nose, throat:



specify abnormality

21. Neck:

Normal	(1
	22
Abnormal	(2

specify abnormality

22. Lymphatic:

Lymphane:	
Normal	(1)
	23
Abnormal	(2)

specify abnormality

23. Chest and lungs:

Normal (1)
Abnormal (2)

specify abnormality

24. Heart:

Normal (1)
Abnormal (2)

specify abnormality

25. Abdomen:

Normal (1)
Abnormal

26. Abdomen abnormality (check all that apply)

a. Ascites: (1) **b.** Obese: (1)

c. Hepatomegaly: (1) (if checked, span from right midclavicular line):

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

27. Extremities:

Normal (1)
Abnormal (2)

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

a. Contractures: (1)
b. Joint hyperextension: (1)
c. Muscle wasting: (1)
d. Fetor: (1)
e. Palmar erythema: (1)
f. Pedal edema: (1)

29. Nervous system:

g. Other (specify):

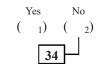
Not performed (0)

Normal (1)

Abnormal (2)

D. Eligibility check

30. Is this the screening visit:



1)

31. Is patient's weight (item 9) <70 kg (154 lbs) or >150 kg (330 lbs):



32. Does patient have Stage 2 hypertension or is systolic blood pressure (average of items 14a, 14c, and 14e) >140 or is diastolic blood pressure (average of items 14b, 14d, and 14f) >90:



33. Is patient's systolic blood pressure (average of items 14a, 14c, and 14e) <90 or is diastolic blood pressure (average of items 14b, 14d, and 14f) <60:



* Check for symptoms of hypotension; if positive for hypotension, patient is ineligible.

Patient ID:				
-------------	--	--	--	--

E. Administrative information

34. Study Physician ID:

35. Study Physician signature:

36. Clinical Coordinator ID:

37. Clinical Coordinator signature:

38. Date form reviewed:

day mon year

PF - Focused Physical Examination

P	urpose: Record focused phy	ysical exam findings.			
W	hen: Visits f04, f12, f36.				
A	dministered by: Study Phys	sician and Clinical Coordinator.			
R	espondent: Patient.				
Ir	STOP-NAFLD SOP Part I. wearing light clothing. She men horizontally at the mid the mid axillary line. Reper Measure the hips at the full	. In brief: height, weight, waist oes should be removed for height dpoint between the highest point eat waist measurements until you	and hips s ht and wei t of the ilia u have two ents until y	blood pressure measurements are f hould be measured with the patient ght measures. Measure the waist are ac crest and the lowest part of the co o measurements within 4 in (10.2 cr you have two measurements within ach visit.	standing and round the abdo- ostal margin in m) of each other.
A. Cen	ter, patient, and visit ident	ification	10.	Waist (standing, at midpoint betw	
1	. Center ID:			of iliac crest and lowest part of co waist measurements until you have	ve two measurements
2	• Patient ID:			within 4 in (10.2 cm) of each othe a. 1st measurement:	r)
3	. Patient code:			a. 1st measurement:	•
4		<u> </u>		b. 2nd measurement:	
	_	-		c. Units:	
	day	mon year		Inches	$\begin{pmatrix} & & 1 \end{pmatrix}$
5	. Visit ID code:	f		Centimeters	(2)
6 7	Form & revision: Study::	_ p _ f _ 2 STOP-NAFLD _9	11.	Hip (standing, at fullest part of the measurements until you have two within 4 in (10.2 cm) of each other	measurements
				a. 1st measurement:	•
B. Mea	asurements			b. 2nd measurement:	
8	. Height (shoes off)				
	a. 1st measurement:			c. Units:	
				Inches	(1)
	b. 2nd measurement:			Centimeters	(2)
		•	12.	Temperature (oral)	
	c. Units:			a. Degrees:	
	Inches	$\begin{pmatrix} & & & & & & & & & & & \\ & & & & & & & $		b. Scale:	
	Centimeters	(2)		Fahrenheit:	(1)
9	. Weight (shoes off)			Centigrade:	(2)
	a. 1st measurement:				
	b. 2nd measurement:	•			
	c. Units:				
	Pounds	(1)			

Kilograms

(₂)

13.	Blood	pressure

a. Systolic, 1st	

		mmHg

breaths/minute

C. Liver signs

16. Liver and spleen:

Normal	(1)
	18
Abnormal	(2)

17. Abnormality (check all that apply)

a. Ascites:	(1)
b. Asterixis:	(1)
c. Contractures:	(1)
d. Fetor:	(1)
e. Hepatomegaly:	(1)

If Yes, span from right midclavicular line:

		cm		
f.	Jaundice:		(1)
g.	Muscle wasting:		(1)
h.	Palmar erythema:		(1)
i.	Pedal edema:		(1)
j.	Spider angiomata:		(1)
k.	Splenomegaly:		(1)
l.	Other (specify):		(1)

D. Administrative information

22. Date form reviewed:

10.	Study Physician ID:	
19.	Study Physician signature:	
20.	Clinical Coordinator ID:	
21.	Clinical Coordinator signature:	

mon

year

PL - Patient Location

When: Screening visit.

Instructions: To be used by clinical center only. Update as needed in the space next to the original entry; date and initial each change.

A. Clinic and patient iden	ntification	
1. Clinic ID:		
2. Patient ID:		
3. Patient code:		
4. Date of visit:		
	mon	year
5. Visit code:	_S	
6. Form & revision:	_p_	
7. Study:	STOP-NAI	FLD <u>9</u>
B. Personal data on patie	nt	
8. Name:		
last name, fi	rst name, middle init	ial
other name	(s) used (if applicabl	e)
9. Home address:		
number and stree	t (apartment # if app	licable)

city, state, zip code

Purpose: To record patient location and contact information.

Patient II	٠.		

10.	Telephone r	umbers
	a. Home:	
		(area code) telephone number
	b. Cell:	
		(area code) telephone number
	c. Work:	
		(area code) telephone number
	d. Pager:	

11. E-mail address:

e-mail address

(area code) telephone number

- 12. Preferred contact information
 - **a.** Telephone number:

(area code) telephone number

b. Best time to call:

time

13. Other addresses for patient (eg, other places where patient lives):

number and street

city, state, zip code

(area code) telephone number

14.	Name of patient's female legal guardian:
	last name, first name, middle initial
15.	Home address and telephone numbers (if different from patient)
	a. Home address:
	number and street (apartment # if applicable)
	city, state, zip code
	b. Daytime telephone number:
	(area code) daytime telephone number
	c. Evening telephone number:
	(area code) evening telephone number
	d. E-mail address:
	e-mail address
16.	Name of patient's male legal guardian:
	last name, first name, middle initial
17.	Home address and telephone numbers (if different from patient)
	a. Home address:
	number and street (apartment # if applicable)
	city, state, zip code
	b. Daytime telephone number:
	(area code) daytime telephone number
	c. Evening telephone number:
	(area code) evening telephone number
	d. E-mail address:

e-mail address

C. Other contacts

18.	Primary physician (this item must be filled out):
	last name, first name, middle initial
	number and street
	city, state, zip code
	(area code) telephone number
19.	Friend or family member who is likely to know the patient's whereabouts
	last name, first name, middle initial
	relationship to patient
	number and street (apartment # if applicable)
	city, state, zip code
	(area code) telephone number
20.	Medical record number:
	medical record number #1
	medical record number #2
	medical record number #3
21.	Insurance number:
	insurance number #1
	insurance number #2
22.	Other local options:

Patient ID:		
I auciii ID.	 	

D. Administrative information

23. Date form reviewed:

day mon year

24. Clinic coordinator PIN: ____ ___

25. Clinic coordinator signature:

STOP-NAFLD

PQ – Pediatric Quality of Life: Parent Report for Teens (Age 13-17)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Parent of teens, age 13-17.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The parent should meet with the Clinical Coordinator and should be trained in completion of the form. Give the parent Flash Card #8, Instructions for Pediatric Quality of Life (Forms PQ and PR) and review the instructions with the parent. The parent should then complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the parent leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Center, patient, and visit identification		B. Administrative information (To be completed by Clinical Coordinator after						
1.	Center ID:		Si	urvey is completed.)				
2.	Patient ID:		8.	How was the Pediatric Quality of Life questionnaire completed:				
3.	Patient code:			Salf administered in English	(`		
4.	Date form completed:			Self-administered in English Self-administered in Spanish Interview in English	(1) 2) 3)		
	day m	non year		Interview in Spanish	(4)		
5.	Visit code:	yeai	9.	Clinical Coordinator a. PIN: b. Signature:				
6.	Form & revision:	<u> </u>		b. Signature.				
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form reviewed:				
				day mon	year			

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

PQ - Pediatric Quality of Life: Parent Report for Teens (Age 13-17)

In the past **ONE month**, how much of a **problem** has your teen had with...

PHYSICAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
11. Walking more than one block:	0	1	2	3	4
12. Running:	0	1	2	3	4
13. Participating in sports activity or exercise:	0	1	2	3	4
14. Lifting something heavy:	0	1	2	3	4
15. Taking a bath or shower by him or herself:	0	1	2	3	4
16. Doing chores around the house:	0	1	2	3	4
17. Having hurts or aches:	0	1	2	3	4
18. Low energy level:	0	1	2	3	4

ЕМО	TIONAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
19.	Feeling afraid or scared:	0	1	2	3	4
20.	Feeling sad or blue:	0	1	2	3	4
21.	Feeling angry:	0	1	2	3	4
22.	Trouble sleeping:	0	1	2	3	4
23.	Worrying about what will happen to him or her:	0	1	2	3	4

Soc	IAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
24.	Getting along with other teens:	0	1	2	3	4
25.	Other teens not wanting to be his or her friend:	0	1	2	3	4
26.	Getting teased by other teens:	0	1	2	3	4
27.	Not able to do things that other teens his or her age can do:	0	1	2	3	4
28.	Keeping up with other teens:	0	1	2	3	4

PedsQl 4.0 - Parent (13-17)

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

SCH	OOL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
29.	Paying attention in class:	0	1	2	3	4
30.	Forgetting things:	0	1	2	3	4
31.	Keeping up with schoolwork:	0	1	2	3	4
32.	Missing school because of not feeling well:	0	1	2	3	4
33.	Missing school to go to the doctor or hospital:	0	1	2	3	4

Thank you for completing this questionnaire.

STOP-NAFLD

PQ – Pediatric Quality of Life: Parent Report for Teens (Age 13-17)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Parent of teens, age 13-17.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The parent should meet with the Clinical Coordinator and should be trained in completion of the form. Use the Spanish version of form PQ for Spanish speaking parents. Give the parent Flash Card #8 (English) or #10 (Spanish), Instructions for Pediatric Quality of Life (Forms PQ and PR) and review the instructions with the parent. The parent should then complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the parent leaves the clinical center. Page 1 should be re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Ce	enter, patient, and visit id	lentification	B. Administrative information (To be completed by Clinical	Coordinator after
1.	Center ID:		survey is completed.)	J
2.	Patient ID:		8. How was the Pediatric Qu questionnaire completed:	ality of Life
3.	Patient code:		Salf administered in Engli	a h ()
4.	Date form completed:		Self-administered in Engli Self-administered in Spani Interview in English	. 1
		<u> </u>	Interview in Spanish	(4)
	day m	oon year	9. Clinical Coordinator	
5.	Visit code:		a. PIN:	
6.	Form & revision:	<u> </u>	b. Signature:	
7.	Study:	STOP-NAFLD <u>9</u>	10. Date form reviewed:	
				<u> </u>
			day mon	year

Affix lab	el here
Patient ID:	
Patient code:	
Visit code:	i

PQ - Inventario Sobre Calidad de Vida Pediátrica: Reporte de Padres para Adolescentes (edades 13-17)

En el mes pasado (UN mes), cuánto de un problema tiene su niño tenía con...

FUNCIONAMIENTO FÍSICO (problemas con)	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
11. Caminado más de una cuadra:	0	1	2	3	4
12. Corriendo:	0	1	2	3	4
13. Participando en actividades deportivas o ejercicios:	0	1	2	3	4
14. Levantando algo pesado:	0	1	2	3	4
15. Tomando una ducha o tina por sí mismo(a):	0	1	2	3	4
16. Haciendo quehaceres en casa:	0	1	2	3	4
17. Teniendo dolores o molestias:	0	1	2	3	4
18. Poca energía:	0	1	2	3	4

FUN con	CIONAMENTO EMOCIONAL (problemas .)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
19.	Sintiéndose asustado o con miedo:	0	1	2	3	4
20.	Sintiéndose triste o decaído:	0	1	2	3	4
21.	Sintiéndose enojado:	0	1	2	3	4
22.	Dificultades para dormir:	0	1	2	3	4
23.	Preocupándose por lo que le vaya a pasar:	0	1	2	3	4

FUN	CIONAMIENTO SOCIAL (problemas con)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
24.	Llevándose bien con otros adolescentes:	0	1	2	3	4
25.	Otros adolescentes no queriendo ser amigos de él o élla:	0	1	2	3	4
26.	Otros adolescentes burlándose de él o élla:	0	1	2	3	4

PedsQI 4.0 - Parent (13-17)

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Patient code:					
Visit code:					
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FUN	CIONAMIENTO SOCIAL (problemas con)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
27.	No pudiendo hacer cosas que otros adolescentes de su edad pueden hacer:	0	1	2	3	4
28.	Pudiendo mantenerse al igual con otros adolescentes:	0	1	2	3	4

FUN con	CIONAMENTO ESCOLAR (problemas)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
29.	Poniendo atención en clase:	0	1	2	3	4
30.	Olvidando cosas:	0	1	2	3	4
31.	Manteniéndose al día con actividades escolares:	0	1	2	3	4
32.	Faltando a la escuela porque no se siente bien:	0	1	2	3	4
33.	Faltando a la escuela para ir al doctor o al hospital:	0	1	2	3	4

¡Gracias por llenar este cuestionario!

STOP-NAFLD

PR – Pediatric Quality of Life: Parent Report for Children (Age 8-12)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Parent of child, age 8-12.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The parent should meet with the Clinical Coordinator and should be trained in completion of the form. Give the parent Flash Card #8, Instructions for Pediatric Quality of Life (Forms PQ and PR) and review the instructions with the parent. The parent should then complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the parent leaves the clinical center. Page 1 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Ce	enter, patient, and visit ic	dentification		Iministrative information To be completed by Clinical Coordina	tor after	
1.	Center ID:			urvey is completed.)	ý	
2.	Patient ID:		8.	How was the Pediatric Quality of Li questionnaire completed:	fe	
3.	Patient code:			Calf a desimination of in English	(`
4.	Date form completed:			Self-administered in English Self-administered in Spanish Interview in English	(1) 2) 3)
		-		Interview in Spanish	(4)
	day n	non year	9.	Clinical Coordinator		
5.	Visit code:		,.	a. PIN: b. Signature:		
6.	Form & revision:	<u> </u>		<u> </u>		
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form reviewed:		
				day mon	year	

1 of 3

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

PR - Pediatric Quality of Life: Parent Report for Children (Age 8-12)

In the past **ONE month**, how much of a **problem** has your child had with...

PHY	SICAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
11.	Walking more than one block:	0	1	2	3	4
12.	Running:	0	1	2	3	4
13.	Participating in sports activity or exercise:	0	1	2	3	4
14.	Lifting something heavy:	0	1	2	3	4
15.	Taking a bath or shower by him or herself:	0	1	2	3	4
16.	Doing chores around the house:	0	1	2	3	4
17.	Having hurts or aches:	0	1	2	3	4
18.	Low energy level:	0	1	2	3	4

ЕМО	TIONAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
19.	Feeling afraid or scared:	0	1	2	3	4
20.	Feeling sad or blue:	0	1	2	3	4
21.	Feeling angry:	0	1	2	3	4
22.	Trouble sleeping:	0	1	2	3	4
23.	Worrying about what will happen to him or her:	0	1	2	3	4

Soc	IAL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
24.	Getting along with other children:	0	1	2	3	4
25.	Other kids not wanting to be his or her friend:	0	1	2	3	4
26.	Getting teased by other children:	0	1	2	3	4
27.	Not able to do things that other children his or her age can do:	0	1	2	3	4
28.	Keeping up when playing with other children:	0	1	2	3	4

PedsQI 4.0 - Parent (8-12)

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Patient ID:
Patient code:
Visit code:
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SCHOOL FUNCTIONING (problems with)		Never	Almost Never	Some- times	Often	Almost Always
29.	Paying attention in class:	0	1	2	3	4
30.	Forgetting things:	0	1	2	3	4
31.	Keeping up with schoolwork:	0	1	2	3	4
32.	Missing school because of not feeling well:	0	1	2	3	4
33.	Missing school to go to the doctor or hospital:	0	1	2	3	4

Thank you for completing this questionnaire.

STOP-NAFLD

PR – Pediatric Quality of Life: Parent Report for Children (Age 8-12)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Parent of child, age 8-12.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The parent should meet with the Clinical Coordinator and should be trained in completion of the form. Use the Spanish version of form PR for Spanish speaking parents. Give the parent Flash Card #8 (English) or #10 (Spanish), Instructions for Pediatric Quality of Life (Forms PQ and PR) and review the instructions with the parent. The parent should then complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the parent leaves the clinical center. Page 1 should be re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Ce	enter, patient, and visit ic	dentification	B. Administrative infor	<mark>mation</mark> Clinical Coordinator afi	er	
1.	Center ID:		survey is completed.)			
2.	Patient ID:		8. How was the Pedi questionnaire com	iatric Quality of Life appleted:		
3.	Patient code:		Salf administered	in English	(`
4.	Date form completed:		Self-administered Self-administered Interview in Engli	in Spanish ish	(1) 2) 3)
	day m	non year	Interview in Span	ish	(₄)
5.	Visit code:		9. Clinical Coordina a. PIN:	tor		
6.	Form & revision:	<u>p</u> r <u>1</u>	b . Signature:			
7.	Study:	STOP-NAFLD 9	10. Date form review	ed:		
					Vear	

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

PR - Inventario Sobre Calidad de Vida Pediátrica: Reporte de Padres para Niños (edades 8-12)

En el mes pasado (UN mes), cuánto de un problema tiene su niño tenía con...

FUN	NCIONAMIENTO FÍSICO (problemas con)	NTO FÍSICO (problemas con) Nunca Casi nunca		Algunas Veces	A Menudo	Casi Siempre
11.	Caminado más de una cuadra:	0	1	2	3	4
12.	Corriendo:	0	1	2	3	4
13.	Participando en actividades deportivas o ejercicios:	0	1	2	3	4
14.	Levantando algo pesado:	0	1	2	3	4
15.	Tomando una ducha o tina por sí mismo(a):	0	1	2	3	4
16.	Haciendo quehaceres en casa:	0	1	2	3	4
17.	Teniendo dolores o molestias:	0	1	2	3	4
18.	Poca energía:	0	1	2	3	4

FUN con	CIONAMENTO EMOCIONAL (problemas .)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
19.	Sintiéndose asustado o con miedo:	0	1	2	3	4
20.	Sintiéndose triste o decaído:	0	1	2	3	4
21.	Sintiéndose enojado:	0	1	2	3	4
22.	Dificultades para dormir:	0	1	2	3	4
23.	Preocupándose por lo que le vaya a pasar:	0	1	2	3	4

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

FUN	CIONAMIENTO SOCIAL (problemas con)	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
24.	Llevándose bien con otros niños:	0	1	2	3	4
25.	Otros niños no queriendo ser amigos de él o élla:	0	1	2	3	4
26.	Otros niños burlándose de él o élla:	0	1	2	3	4
27.	No pudiendo hacer cosas que otros niños de su edad pueden hacer:	0	1	2	3	4
28.	Pudiendo mantenerse al igual con otros niños:	0	1	2	3	4

FUN con	CIONAMENTO ESCOLAR (problemas .)	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
29.	Poniendo atención en clase:	0	1	2	3	4
30.	Olvidando cosas:	0	1	2	3	4
31.	Manteniéndose al día con actividades escolares:	0	1	2	3	4
32.	Faltando a la escuela porque no se siente bien:	0	1	2	3	4
33.	Faltando a la escuela para ir al doctor o al hospital:	0	1	2	3	4

¡Gracias por llenar este cuestionario!

STOP-NAFLD

PW – Pediatric Quality of Life: Child Report (Age 8-12)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Patient, age 8-12.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The patient should meet with the Clinical Coordinator and should be trained in completion of the form. Give the patient Flash Card #7, Instructions for Pediatric Quality of Life (Forms PW and PY) and review the instructions with the patient. The patient should then 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 should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Ce	Center, patient, and visit identification B. Administrative information (To be completed by Clinical Coordinator after						
1.	Center ID:		<u>s</u> ı	irvey is completed	.)	v	
2.	Patient ID:		8.	How was the Perquestionnaire co	diatric Quality of Li mpleted:	fe	
3.	Patient code:		-	Self-administere	d in English	(`
4.	Date form completed:			Self-administere Interview in Eng	d in Spanish lish	(1) 2) 3)
	day n	non year	-	Interview in Spa	nish	(4)
5.	Visit code:		9.	Clinical Coordin a . PIN: b . Signature:	ator		
6.	Form & revision:	<u> </u>	-	b. Signature.			
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form review	ved:		
					mon	year	

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

PW - Pediatric Quality of Life: Child Report (Age 8-12)

In the past **ONE month**, how much of a **problem** has this been for you...

АВО	UT MY HEALTH AND ACTIVITIES (problems with)	Never	Almost Never	Some- times	Often	Almost Always
11.	It is hard for me to walk more than one block:	0	1	2	3	4
12.	It is hard for me to run:	0	1	2	3	4
13.	It is hard for me to do sports activity or exercise:	0	1	2	3	4
14.	It is hard for me to lift something heavy:	0	1	2	3	4
15.	It is hard for me to take a bath or shower by myself:	0	1	2	3	4
16.	It is hard for me to do chores around the house:	0	1	2	3	4
17.	I hurt or ache:	0	1	2	3	4
18.	I have low energy:	0	1	2	3	4

ABOUT MY FEELINGS (problems with)	Never	Almost Never	Some- times	Often	Almost Always
19. I feel afraid or scared:	0	1	2	3	4
20. I feel sad or blue:	0	1	2	3	4
21. I feel angry:	0	1	2	3	4
22. I have trouble sleeping:	0	1	2	3	4
23. I worry about what will happen to me:	0	1	2	3	4

How	I GET ALONG WITH OTHERS (problems with)	Never	Almost Never	Some- times	Often	Almost Always
24.	I have trouble getting along with other kids:	0	1	2	3	4
25.	Other kids do not want to be my friend:	0	1	2	3	4
26.	Other kids tease me:	0	1	2	3	4
27.	I cannot do things that other kids my age can do:	0	1	2	3	4
28.	It is hard to keep up when I play with other kids:	0	1	2	3	4

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

ABOUT SCHOOL (problems with)	Never	Almost Never	Some- times	Often	Almost Always
29. It is hard to pay attention in class:	0	1	2	3	4
30. I forget things:	0	1	2	3	4
31. I have trouble keeping up with my schoolwork:	0	1	2	3	4
32. I miss school because of not feeling well:	0	1	2	3	4
33. I miss school to go to the doctor or hospital:	0	1	2	3	4

Thank you for completing this questionnaire.

STOP-NAFLD

A

PW – Pediatric Quality of Life: Child Report (Age 8-12)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Patient, age 8-12.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The patient should meet with the Clinical Coordinator and should be trained in completion of the form. Use the Spanish version of form PW for Spanish speaking children. Give the patient Flash Card #7 (English) or #9 (Spanish), Instructions for Pediatric Quality of Life (Forms PW and PY) and review the instructions with the patient. The patient should then 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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

. Ce	enter, patient, and visit ide	entification		ministrative information To be completed by Clinical Coordinator aft	or	
1.	Center ID:			ervey is completed.)	C1	
2.	Patient ID:		8.	How was the Pediatric Quality of Life questionnaire completed:		
3.	Patient code:			Self-administered in English	(`
4.	Date form completed:			Self-administered in Spanish Interview in English	(1) 2) 3)
	day mo	n year		Interview in Spanish	(4)
5.	Visit code:		9.	Clinical Coordinator a. PIN: b. Signature:		
6.	Form & revision:	<u> </u>		2-8		
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form reviewed:		
				day mon	year	

	Affix label here
- Inventario Sobre Calidad de Vida Pediátrica: Reporte de Niños (edades 8-12)	Patient ID: Patient code: Visit code:

PW

En el mes pasado (UN mes), cuánto problema fue ésto para tí...

SOB con	RE MI SALUD Y ACTIVIDADES (problemas	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
11.	Se me hace difícil caminar más de una cuadra:	0	1	2	3	4
12.	Se me hace difícil correr:	0	1	2	3	4
13.	Se me hace difícil practicar deportes o ejercicios:	0	1	2	3	4
14.	Se me hace difícil levantar algo pesado:	0	1	2	3	4
15.	Se me hace difícil bañarme solo en tina o regadera:	0	1	2	3	4
16.	Se me hace difícil hacer quehaceres en la casa:	0	1	2	3	4
17.	Siento dolores o molestias:	0	1	2	3	4
18.	Tengo poca energía:	0	1	2	3	4

SOB	RE MIS EMOCIONES (problemas con)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
19.	Me siento asustado o con miedo:	0	1	2	3	4
20.	Me siento triste o decaído:	0	1	2	3	4
21.	Me siento enojado:	0	1	2	3	4
22.	Tengo dificultades para dormir:	0	1	2	3	4
23.	Me preocupo por lo que me vaya a pasar:	0	1	2	3	4

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

CÓM con	O ME LLEVO CON LOS DEMÁS (problemas	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
24.	Tengo problemas llevándome con otros niños:	0	1	2	3	4
25.	Otros niños no quieren ser mis amigos:	0	1	2	3	4
26.	Otros niños se burlan de mí:	0	1	2	3	4
27.	No puedo hacer cosas que otros niños de mi edad pueden hacer:	0	1	2	3	4
28.	Se me hace difícil mantenerme al igual que otros niños cuando juego con éllos:	0	1	2	3	4

SOB	RE LA ESCUELA (problemas con)	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
29.	Se me hace difícil poner atención en clase:	0	1	2	3	4
30.	Se me olvidan las cosas:	0	1	2	3	4
31.	Tengo dificultad para mantenerme con actividades escolares:	0	1	2	3	4
32.	Falto a la escuela por no sentirme bien:	0	1	2	3	4
33.	Falto a la escuela para ir al doctor o al hospital:	0	1	2	3	4

¡Gracias por llenar este cuestionario!

STOP-NAFLD

PY – Pediatric Quality of Life: Teen Report (Age 13-17)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Patient, age 13-17.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The patient should meet with the Clinical Coordinator and should be trained in completion of the form. Give the patient Flash Card #7, Instructions for Pediatric Quality of Life (Forms PY and PW) and review the instructions with the patient. The patient should then 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 should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

A. Ce	A. Center, patient, and visit identification			B. Administrative information (To be completed by Clinical Coordinator after						
1.	Center ID:		SU	urvey is completed.)						
2.	Patient ID:		8.	How was the Pediatric Quality of Life questionnaire completed:						
3.	Patient code:			C-16 - 1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-	(,				
4.	Date form completed:			Self-administered in English Self-administered in Spanish Interview in English	(1) 2) 3)				
				Interview in Spanish	(4)				
5.	day m	oon year	9.	Clinical Coordinator a. PIN: b. Signature:						
6.	Form & revision:	_p _y _1		S. Signatore.						
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form reviewed:						
				day mon	year					

PY	- Pediatric Quality of Life:
	Adolescent (Age 13-17)

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

In the past **ONE month**, how much of a **problem** has this been for you...

ABO	UT MY HEALTH AND ACTIVITIES (problems with)	Never	Almost Never	Some- times	Often	Almost Always
11.	It is hard for me to walk more than one block:	0	1	2	3	4
12.	It is hard for me to run:	0	1	2	3	4
13.	It is hard for me to do sports activity or exercise:	0	1	2	3	4
14.	It is hard for me to lift something heavy:	0	1	2	3	4
15.	It is hard for me to take a bath or shower by myself:	0	1	2	3	4
16.	It is hard for me to do chores around the house:	0	1	2	3	4
17.	I hurt or ache:	0	1	2	3	4
18.	I have low energy:	0	1	2	3	4

ABOUT MY FEELINGS (problems with)	Never	Almost Never	Some- times	Often	Almost Always
19. I feel afraid or scared:	0	1	2	3	4
20. I feel sad or blue:	0	1	2	3	4
21. I feel angry:	0	1	2	3	4
22. I have trouble sleeping:	0	1	2	3	4
23. I worry about what will happen to me:	0	1	2	3	4

How	I GET ALONG WITH OTHERS (problems with)	Never	Almost Never	Some- times	Often	Almost Always
24.	I have trouble getting along with other teens:	0	1	2	3	4
25.	Other teens do not want to be my friend:	0	1	2	3	4
26.	Other teens tease me:	0	1	2	3	4
27.	I cannot do things that other teens my age can do:	0	1	2	3	4
28.	It is hard to keep up with my peers:	0	1	2	3	4

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Patient ID:					
Patient code:					
Visit code:					

ABOUT SCHOOL (problems with)	Never	Almost Never	Some- times	Often	Almost Always
29. It is hard to pay attention in class:	0	1	2	3	4
30. I forget things:	0	1	2	3	4
31. I have trouble keeping up with my schoolwork:	0	1	2	3	4
32. I miss school because of not feeling well:	0	1	2	3	4
33. I miss school to go to the doctor or hospital:	0	1	2	3	4

Thank you for completing this questionnaire.

STOP-NAFLD

PY – Pediatric Quality of Life: Teen Report (Age 13-17)

Purpose: To obtain the patient's quality of life.

When: Visits s, f24, and f36.

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

Respondent: Patient, age 13-17.

Instructions: The Clinical Coordinator should complete section A below and attach a label to pages 2-3. The patient should meet with the Clinical Coordinator and should be trained in completion of the form. Use the Spanish version of form PY for Spanish speaking patients. Give the patient Flash Card #7 (English) or #9 (Spanish), Instructions for Pediatric Quality of Life (Forms PW and PY) and review the instructions with the patient. The patient should then 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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQLTM creators to use their forms in NASH CRN studies. These forms should not be used or copied for non NASH CRN purposes.

Ce	enter, patient, and visit ide	ntification	B. Administrative information (To be completed by Clinical Coordinator after						
1.	Center ID:			vey is completed.)	er				
2.	Patient ID:		8.	How was the Pediatric Quality of Life questionnaire completed:					
3.	Patient code:			•					
4.	Date form completed:			Self-administered in English Self-administered in Spanish Interview in English	(1) 2) 3)			
	day mor	year		Interview in Spanish	(4)			
5.	Visit code:		9.	Clinical Coordinator a. PIN: b. Signature:					
6.	Form & revision:	<u>p</u> <u>y</u> <u>1</u>		2. Signature.					
7.	Study:	STOP-NAFLD <u>9</u>	10.	Date form reviewed:		—			
					vear				

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

PY - Inventario Sobre Calidad de Vida Pediátrica: Reporte de Adolescentes (edades 13-17)

En el mes pasado (UN mes), cuánto problema fue ésto para tí...

SOB con	RE MI SALUD Y ACTIVIDADES (problemas	Nunca	Casi nunca	Algunas Veces	A Menudo	Casi Siempre
11.	Se me hace difícil caminar más de una cuadra:	0	1	2	3	4
12.	Se me hace difícil correr:	0	1	2	3	4
13.	Se me hace difícil practicar deportes o ejercicios:	0	1	2	3	4
14.	Se me hace difícil levantar algo pesado:	0	1	2	3	4
15.	Se me hace difícil bañarme solo en tina o regadera:	0	1	2	3	4
16.	Se me hace difícil hacer quehaceres en la casa:	0	1	2	3	4
17.	Siento dolores o molestias:	0	1	2	3	4
18.	Tengo poca energía:	0	1	2	3	4

SOB	RE MIS EMOCIONES (problemas con)	Nunca	Casi Nunca	Algunas Veces	A Menudo	Casi Siempre
19.	Me siento asustado o con miedo:	0	1	2	3	4
20.	Me siento triste o decaído:	0	1	2	3	4
21.	Me siento enojado:	0	1	2	3	4
22.	Tengo dificultades para dormir:	0	1	2	3	4
23.	Me preocupo por lo que me vaya a pasar:	0	1	2	3	4

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

	CÓMO ME LLEVO CON LOS DEMÁS (problemas con)		Casi nunca	Algunas Veces	A Menudo	Casi Siempre
24.	Tengo problemas llevándome con otros adolescentes:	0	1	2	3	4
25.	Otros adolescentes no quieren ser mis amigos:	0	1	2	3	4
26.	Otros adolescentes se burlan de mí:	0	1	2	3	4
27.	No puedo hacer cosas que otros adolescentes de mi edad pueden hacer:	0	1	2	3	4
28.	Se me hace difícil mantenerme al igual con mis compañeros:	0	1	2	3	4

SOB	SOBRE LA ESCUELA (problemas con)		Casi nunca	Algunas Veces	A Menudo	Casi Siempre
29.	Se me hace difícil poner atención en clase:	0	1	2	3	4
30.	Se me olvidan las cosas:	0	1	2	3	4
31.	Tengo dificultad para mantenerme con actividades escolares:	0	1	2	3	4
32.	Falto a la escuela por no sentirme bien:	0	1	2	3	4
33.	Falto a la escuela para ir al doctor o al hospital:	0	1	2	3	4

¡Gracias por llenar este cuestionario!

RC - Rescreen in STOP-NAFLD

Purpose: To rescreen a patient who was previously found to be ineligible for the STOP-NAFLD Trial due to a temporary ineligibility. This form must be the first form completed and keyed for the patient for this screening cycle (the date in item 4 of this form will be the date that the 60-day screening window starts). The original RG form completed for the patient must remain in the data system. New screening labels will be available for printing upon keying this form.

When: Visit code s.

Administered by: Clinical Coordinator.

Respondent: None.

Instructions: Complete this form for a patient who was previously found to be ineligible for STOP-NAFLD due to a temporary ineligibility and who now wants to rescreen for STOP-NAFLD. In general, the patient must complete all STOP-NAFLD screening data collection anew and all previously keyed STOP-NAFLD screening forms should be deleted from the data system except the RG and possibly the CG form. If needed, update section C (only education and employment history) of the RG form and update the keyed record (you cannot delete the RG form); note that the patient's age will not change since it is based on the date of the RG form. If any changes are made in section C, the review date in section F should be updated. If blood was collected successfully for the Genetics Repository, a new sample does not need to be collected and the previously completed CG form may remain unchanged in the data system. Plasma and serum must be collected anew.

A. Center, patient, and visit identification		C. Administrative infor	mation		
1. Center ID:		9. Clinical Coordinator	PIN:		
2. Patient ID:			10. Clinical Coordinator	signature:	
3. Patient code:					
4. Date of visit:			11. Date form reviewed:		_
day	mon	year	day	mon	year
5. Visit code:	S_				
6. Form & revision:	_r_	c1_			
7. Study:	STOP-NA	AFLD 9			
B. STOP-NAFLD partie	cipation				
8. Date in item 4 of ori RG form:	ginal STOP-NA	FLD			
	mon	vear			

RD – Study Drug Dispensing and Return

Purpose: To explain STOP-NAFLD study drug prescription dose instructions and to record dispensing, return of study drug and study drug compliance.

When: Visits rz, f02, f04, f12 and f24. Use visit code "n" if study drug is dispensed or returned at a time other than study visits or if a second form is needed at a visit to document returned study drug.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Instructions: STOP-NAFLD study drug will be taken once a day in the morning. Children should be instructed to take one 50 mg capsule each morning for the first week, then two 50 mg capsules each morning for weeks 2-24.

The children and their parents/guardians should be queried about the use of study medication at all visits. The clinical coordinator should count and record the number of capsules remaining in the study drug bottles when a patient returns used study drug bottles to the clinical center.

A. Center, patient, and visit identification

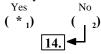
- 1. Center ID:
- 2. Patient ID:
- **3.** Patient code:
- **4.** Date of visit:



- 5. Visit code:
- **6.** Form & revision: <u>r d 2</u>
- 7. Study: STOP-NAFLD 9

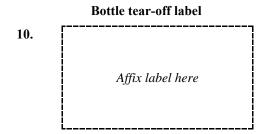
B. Study drug dispensing

8. Will study drug be dispensed today:



* Give dosing instruction sheet to patient.

9. How many bottles were dispensed: (01-02)



11.

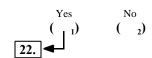
Affix label here

12. How was the study drug dispensed to the patient (*check only one*):

In person	(1)
Mail	(2)
Other (specify):	(3)

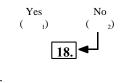
specify

13. Is this the RZ visit:



C. Study drug return

14. Were any bottles returned at this visit:



15. Number of bottles returned:

(01-02)	
h	
b.	

Bottle No.		Number of capsules returned
16.		(000-200)
17.		(000-200)

Patient ID:		

D. Study drug compliance

18. Is the patient currently taking the STOP-NAFLD study drug at the dose prescribed:

Yes	No
(1)	(2
19. ◀	

a. Date study drug was stopped:

_		_
day	mon	year

b. Was the study drug stopped before the end of the intended treatment period due to trial termination:

19. How many capsules per day has the patient been taking since the last study visit:

20. Was the dose tolerated by the patient *(check only one)*:

Yes (1)

Patient experienced mild side effects, but medication dose was not changed (2)

No, patient experienced side effects and will not take the dose prescribed at randomization $(*_3$

No, patient experienced side effects and the medication was stopped (*4)

21. The prescribed number of capsules to be taken each morning after this visit:

IMPORTANT: You must enter this form into the data system **within 48 hours** of dispensing study drug to the participant.

- E. Administrative information
- **22.** Study Physician PIN:
- 23. Study Physician signature:
- **24.** Clinical Coordinator PIN:
- **25.** Clinical Coordinator signature:
- **26.** Date form reviewed:

		<u>-</u>
day	mon	year

^{*} If patient experienced severe and unanticipated side effects, complete the SR form.

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

When: At first screening visit (s).

Administered by: Clinical Coordinator.

Respondent: Patient and guardian.

Instructions: Use Flash Cards as instructed. Do not assign a new ID if patient has previously been assigned an ID for a NASH CRN study. If is checked for any item, the patient is not eligible for STOP-NAFLD and the form should not be keyed.

A. Center	natient	and	vicit	iden	tifica	tion

- **1.** Center ID: ____ ___ ____
- **2.** Patient ID: ____ ___ ____
- **3.** Patient code: ____ ___
- **4.** Visit date:
- day mon year
- 7. Study: STOP-NAFLD 9

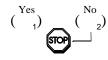
B. Consent

5. Visit code:

8. After reviewing the existing records (e.g., liver biopsy, elevated aminotransferases, and/or history) does the study physician feel that the patient may be suitable for the study:



9. Has the patient (or patient's guardian) signed the STOP-NAFLD informed consent statement:



10. Has the patient signed the STOP-NAFLD informed assent statement:

Yes	(1
No	(STOP) ²
Not using assent	_ (₃
Not using assent for this age child	(,

C. Information about patient

11. Date of birth:

	- _	
day	month	year
Record	4-digit year for da	te of birth.

- **13.** Is the patient's age at least 8 years old and less than 18 years:



14. Gender:

Male	(1
Female	(2

15. Ethnic category (show the patient/guardian Flash Card #1 and ask the respondent to pick the category that describes the patient best; check only one):

Not Hispanic, not Latino, not Latina	(2)
	17. —	

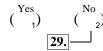
16.	16. What describes the patient's Hispanic, Latino, or Latina origin best (show the pa- tient/guardian Flash Card #1 and ask the respon- dent to pick the subcategory that best describes the patient's Hispanic, Latino, or Latina origin; check			20. Combined annual income before taxes of all members of patient's household (show ian Flash Card #4 and ask respondent to category that describes the patient's chousehold income best; check only one):	w gu pick comb	k the
	only one):			Less than \$15,000	(1)
	Mexican	(1)	\$15,000 - \$29,999	(2)
	Puerto Rican	(2)	\$30,000 - \$49,999	(3)
	Cuban	(3)	\$50,000 or more	((ړ
	South or Central American	(4)		•	7
	Other Spanish culture or origin specify	(₅)	21. Current age of patient's mother, stepmother, or female guardian (show patient/parent Flash Card #5; chone):	neck	only
17.	Racial category (show the patient/guardic Card #2 and ask the respondent to pick gory or categories that describe the paticheck all that apply)	the c	ate-	Not applicable (mother is deceased or patient has no stepmother or female guardian) 19 or younger	(0) 1)
	a. American Indian or Alaska Native:	(1)	20-29 years	(2)
	b. Asian:	(1)	30-39 years	(3)
	c. Black, African American, Negro, or	`	12	40-49 years	(4)
	Haitian:	(1)	50-59 years	(5)
	d. Native Hawaiian or other Pacific Islander:	(1)	60 years or older	(6)
18.	e. White:f. Patient/guardian refused: In what country was the patient born	(1) 1)	22. Highest educational level achieved by patient's mother, stepmother, or female guardian (show patient/parent Flash Caeducation of mother or female guardia known, record as "n"; check only one):		
	(check only one):			Never attended school	(0
	Continental US (includes Alaska) or			Did not complete high school	(1)
	Hawaii	(1)	Completed high school	(2)
	Other, (specify):	(₂)	Some college or post high school education or training	(3)
	specify			Bachelor's degree or higher	(4)
19.	Patient's current grade level in school (or home school) (show the patient/guardic Card #3 and ask the respondent to pick	an Fi the c	ate-	23. Current age of patient's father, stepfather or male guardian (<i>show patient/parent Fl #5; check only one</i>):		Card
	gory that describes the patient best; if time, report grade entering in the fall; cone):	f sum heck o	mer only	Not applicable (father is deceased or patient has no stepfather or male guardian)	(0
	Grades 1 to 5	(1)	19 or younger	(1)
	Grades 6-8	(2)	20-29 years	(2)
	Grades 9-12	(3)	30-39 years	(3)
	Other, (specify):	((ر	40-49 years	(3) 4)
		`	4′	50-59 years	(4) 5)
	specify			60 years or older	(5)
	apata.j			oo years or order	(6)

24. Highest educational level achieved by patient's father, stepfather, or male guardian (show patient/parent Flash Card #6; if education of father or male guardian is unknown, record as "n"; check only one):

Never attended school	(0
Did not complete high school	(1)
Completed high school	(2)
Some college or post high school education or training	(3)
Bachelor's degree or higher	((۱

D. Previous registration in a NASH CRN study

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



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

specify		
e. Other, (specify):	(1
d. CyNCh:	(1
c. NAFLD Pediatric Database 2:	(1
b. TONIC:	(1
a. NAFLD Database:	(1/

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

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

30.

E. ID assignment

(If a STOP or ineligible 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.)

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

CCCC ####,zzz

	A .1	••_4	4	· C	4
H. A	Aam	ıınıstı	rative	intor	mation

- **30.** Clinical Coordinator PIN: ____ ___
- **31.** Clinical Coordinator signature:
- **32.** Date form reviewed:

day	mon	year

RZ - Randomization Checks

Purpose: To check eligibility for STOP-NAFLD with respect to items not checked elsewhere on STOP-NAFLD screening forms and record reasons for ineligibility for patients found to be ineligible.

5. Visit code:

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient and Clinical Coordinator.

Instructions: This form may be initiated at any time. If the patient proceeds to randomization, it must be reviewed on the day of randomization. Patients of childbearing potential must complete the randomization day pregnancy test at the clinic on the day of randomization.

If m is checked for any item, complete the entire form, but note that the patient may not participate in the STOP-NAFLD trial. If an item has not been assessed because the patient is ineligible, write "m" (missing) next to that item. This form must be keyed for each patient for whom form RG was completed.

A. Center, patient, visit, and study identification

1.	Center ID:			
2.	Patient ID:			
3.	Patient code:			
4.	Visit date (date this form to	is initi	ated):	

- day mon year
- 6. Form & revision: <u>r z 1</u>

STOP-NAFLD 9 7. Study:

B. Diabetes Status

8. In the judgment of the Study Physician and based on the patient's medical history and laboratory results, does the patient have diabetes:



9. Is the patient's diabetes poorly controlled (HbA1c greater than 9.5% within the past 30 days):



C. Alcohol use exclusions

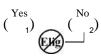
10. Does the patient have a history of significant alcohol intake:



11. In the judgment of the Study Physician and/or Clinical Coordinator, can the patient reliably quantify his/her (past and *current*) alcohol intake:



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



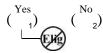
D. Laboratory test exclusions

13. Hepatic Decompensation

a. Is the patient's serum albumin less than 3.2 g/dL:



b. Is the patient's INR greater than 1.3:



c. Is the patient's direct bilirubin greater than 1.3 mg/dL:



d. Does the patient have a history of esophageal varices, ascites, or hepatic encephalopathy:



- 14. Other laboratory measures
 - a. Is serum ALT greater than 300 IU/L:



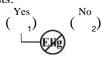
b. Is serum ALT less than 50 IU/L:



c. Is the patient's platelet count less than 100,000 cells/mm³:

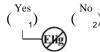


d. Tests are outside time window and clinic chose not to repeat tests:



E. Medication use exclusions

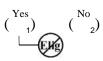
15. Use of drugs associated with NAFLD for more than 2 consecutive weeks in the past 12 months:



16. Current use of any antihypertensive medications, potassium, or lithium:



17. Current daily use of NSAIDS:



18. Initiation of new treatment with Vitamin E or metformin in past 90 days or plans to alter or stop dose over next 24 weeks:

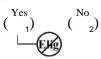


F. Other chronic liver disease exclusions

19. Does the patient have ongoing autoimmune liver disease defined by liver histology:



20. Does the patient have Wilson's disease defined by ceruloplasmin below the lower limit of normal and liver histology consistent with Wilson's disease:



21. Does the patient have alpha-1-antitrypsin (A1AT) genotype ZZ or SZ:

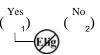


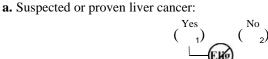
22. Does the patient have a transferrin saturation greater than 45% with histological evidence of iron overload (3+ or 4+ stainable iron on liver biopsy):



- **23.** Do any of the patient's assessments show evidence of other chronic liver disease
- 29. NAFLD activity score (NAS) less than 3:

28. Local pathologist did not find NAFLD:





H. Other medical exclusions

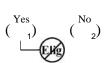
b. Hepatitis B (HBsAg):

30. History of bariatric surgery or plans to have bariatric surgery during the STOP-NAFLD trial:

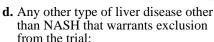


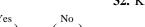


31. History of biliary diversion:



c. Hepatitis C (HCV RNA or anti-HCV):



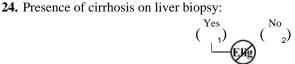


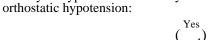
32. Known positivity for HIV infection:



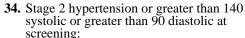
G. Liver biopsy exclusions

33. History of hypotension or history of

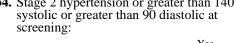




25. Inability to safely undergo a liver biopsy:



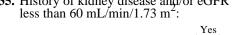






- 26. Biopsy out of window and patient chose not to repeat:
- 35. History of kidney disease and/or eGFR







- 27. Biopsy inadequate for scoring and patient chose not to repeat:
- 36. Known active substance abuse (inhaled or injected) in the past 12 months:



Form RZ

37. Known allergy to losartan potassium or other angiotensin receptor blocker:



38. Known active, serious medical disease with a likely life-expectancy of less than five years:



39. Participant in an IND trial in the past 150 days:



40. Other conditions which, in the opinion of the investigator, would impede compliance or hinder completion of the study:



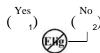
I. Weight exclusion

41. Weight less than 70 kilograms (154 pounds) or greater than 150 kilograms (330 pounds) at screening:



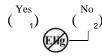
J. Birth control exclusion

42. In the judgment of the Study Physician and/or Clinical Coordinator, is the patient (female of childbearing potential) willing to use effective birth control methods to avoid pregnancy during the 24 weeks of treatment (check "Yes" if patient is male or not of childbearing potential):



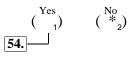
K. Check on ability to swallow study medication

43. In your judgment (Study Physician/Clinical Coordinator), is the patient able to swallow the STOP-NAFLD study medications (if you are unsure, you may ask the patient to swallow an empty capsule):



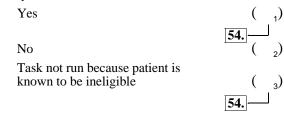
L. Eligibility check on day of randomization

44. Was an ineligibility condition checked or an eligibility not ascertained in items 9-43:

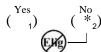


*Key forms RG, AD, BH, BP, BQ, CG, HF, LR, LS, PE, PQ/PR, PW/PY, and SD. Run the Randomization Task on your clinic data system.

45. Were any stops or ineligible conditions other than "missing form RZ" identified by the Randomization Task:

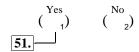


46. Based on today's physical examination, does the patient feel well today:

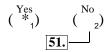


*Defer randomization until the patient feels well; when the patient returns to attempt randomization again, review all items on this form and update each item as needed.

47. Is the patient male:



48. Is the patient of childbearing potential:



*Administer pregnancy test.

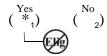
49. Is the patient pregnant (positive pregnancy test on the day of randomization):



*Go to item 54.

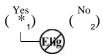
Patient ID:		

50. Is the patient currently breast feeding



*Go to item 54.

51. In the Study Physician's judgment, is there any reason to exclude the patient from randomization:



*If Yes, specify reason and then go to item 54:

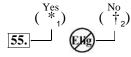
specify reason

52. Did you review the use of concomitant medications with the patient and parents:



*Review concomitant medications with the patient and parents prior to randomizing patient.

53. Does the patient still consent to randomization (*you should ask the patient to orally affirm his/her consent*):



*Go to item 55 and complete this form. Then key this form and run the Randomization Task on your clinic data system to randomize the patient.

†Complete items 54-59 and key the form. The form must be keyed to document the reasons for ineligibility for STOP-NAFLD.

M. Reasons for ineligibility for ineligible patients

Note: Complete this section for ineligible patients only.

54. Reason for ineligibility (check all that apply)

a. Reason covered in items 9-53: (

b. Other reason not covered on this form (specify):

specify

N.	Adm	inistr	ative	inform	nation
١٦.	Aum	шизи	auve	шииш	เลนบม

55. Study Physician PIN:

56. Study Physician signature:

57. Clinical Coordinator PIN:

58. Clinical Coordinator signature:

Ciliiicui	Coordinator	Signature.	
_			٠

59. Date form reviewed

(Note: This form must be reviewed on the day of randomization; if it was keyed prior to the randomization day, update it, re-review it on the day of randomization, and key the revised date of review.):

dav	mon	vear

SD - Liver Biopsy Materials Documentation

Purpose: To document that the liver biopsy required for screening was obtained under the time restrictions required by the protocol and to document whether liver tissue was obtained for banking. The number and type of slides available for archival at the Data Coordinating Center are noted. If slides cannot be archived at the Data Coordinating Center, the source of the slides and the time by which the slides must be returned to the clinical center are recorded.

When: Visits s and as needed for biopsies at interim times.

By whom: Clinical Coordinator in consultation with the Study Pathologist.

Instructions: This form provides information about the slides from the biopsy and alerts the DCC to expect receipt of slides from the biopsy at the Data Coordinating Center. It also provides a record of the source of the slides, the number and type of stained slides available for review at the clinical center, the need (if any) to borrow those stained slides or provision of those stained slides to the NASH CRN without requiring return of the slides, and the number of unstained slides to be provided to the NASH CRN. A copy of the original surgical pathology report for the biopsy must be obtained; the patient's name should be blacked out, the report should be annotated with the patient's NASH CRN ID number and code, and the annotated report should be stapled to the back of this form. The surgical pathology report documents the date of biopsy. The slides should be labeled using the labels provided by the DCC. For unstained slides use permanent labels with sequence numbers 01-60, the borrowed slides should be labeled with removable overlabels with sequence numbers 81-90. Note: if biopsy slides were already sent to the DCC for DB2, they do not need to be sent again.

A.	Center.	patient	and	visit	iden	tification	n
----	---------	---------	-----	-------	------	------------	---

1.	Center ID:		 	

2. Patient ID:				
-----------------------	--	--	--	--

2	Patient code:	
э.	Patient code.	

4. Date form initia	ited:		
day	,	mon	vear

5. Visit code:		 	

B. Surgical pathology report

8. Is a copy of the report annotated with the patient's NASH CRN ID number and code and with name blacked out attached to this form:



* Obtain a copy of the report, annotate it, and attach it. You can use one of the pathology labels to annotate the report.

9. Biopsy information

a. Date of biopsy specified on the surgical pathology report:

	day	mon	year
	specimen ob	tained from	
(check	k only one):		
Right			(1
Left			(2
Unkn	own		(3/

C. Requirements for screening biopsy

- **11.** Is the date in item 9a within 730 days of the anticipated date of randomization:

* Biopsy date must be within 730 days of randomization.

D. Biopsy specimens and stained slides at the clinical center

12. What stained slides from the biopsy are available at the clinical center (*check all that apply*)

a. H & E sta	in:	(1)

E. Unstained slides to be sent to the DCC

13. Were slides for this biopsy previously sent to the DCC in DB2:

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

* Additional slides do not need to be sent to the DCC.

14. Are unstained slides available for sending to the DCC:



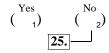
- **15.** How many unstained slides will be sent to the DCC:
- **16.** What are the slide sequence numbers for those slides (*from the NASH CRN labels on each slide use permanent labels, sequence numbers 01-60*):

01-10

F. Stained slides to be sent to the DCC

(The institution's stained slides must be sent to the DCC only if fewer than 3 unstained slides will be sent to the DCC)

17. Are any stained slides to be sent to the DCC:



- **18.** How many stained slides are to be sent to the DCC:
- **19.** Sequence number of slides to be sent to DCC
 - a. Slide sequence number of H & E stain:

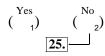
01	Ω	
ο1.	-90	

- b. Slide sequence number of Masson's trichrome stain:

 81-90
- c. Slide sequence number of iron stain:

d. Slide sequence number of other stain:

20. Are any stained slides to be returned to the clinic:



- **21.** How many stained slides are to be returned to the clinic:
- **22.** List sequence numbers of those slides to be returned
 - **a.** Slide sequence number:

81-90	

b. Slide sequence number:

c. Slide sequence number:

d. Slide sequence number:

23. When do the stained slides need to be returned to the clinical center (*check only one*):

Immediately after central review

At the end of the NASH CRN funding period

24. Which pathology department did these slides come from:

NASH CRN clinical center's pathology

department (125. (225

address
address
address

Note: this is the STOP-NAFLD trial record of the source of the slides i.e., where the clinical center should send the slides when they are received back from the DCC.

- G. Administrative information
- **25.** Clinical Coordinator PIN: ____ ____
- **26.** Clinical Coordinator signature:
- **27.** Date form reviewed:

day mon year

SR - Serious Adverse Event/IND Safety Report

Purpose: To report serious adverse events recorded on the Adverse Event Report (AE) form that satisfy the FDA expedited FDA Safety Report requirements outlined in the STOP-NAFLD Trial protocol. In order to satisfy FDA expedited IND Safety Report requirements the event must be SERIOUS, UNEXPECTED, AND have a REASONABLE POSSIBILITY of being caused by STOP-NAFLD study drug, as defined by Title 21 Code of Federal Regulations Part 312.32 IND Safety Reporting:

Serious adverse event or serious suspected adverse reaction. An adverse event or suspected adverse reaction is considered "SERIOUS" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Other medical events may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "REASONABLE POSSIBILITY" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

Unexpected adverse event or unexpected suspected adverse reaction. An adverse event or suspected adverse reaction is considered "**UNEXPECTED**" if it is not listed in the losartan potassium investigator's brochure or is not listed at the specificity or severity that has been observed for your patient.

When: The SR form should be used only for reporting a serious and unexpected adverse event which meets the IND Safety Report criteria as stated above, or when a followup report is needed for a previously completed SR form. When the serious adverse event does not meet the expedited IND Safety Report criteria, use the Adverse Event Report (AE) form to report the event.

Completed by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form **within 1 business day**. The short name (item 24) and the severity grade (item 25) are to be obtained from the NCIs Common Terminology Criteria for Adverse Events v5.0 (CTCAE). The CTCAE document is available at www.nashcrn.com. (Click on Studies then click on STOP-NAFLD). Report the serious adverse event to your IRB per local guidelines. Send the Data Coordinating Center the following:

- 1) A copy of this SR form and corresponding AE form
- 2) A narrative description of the event that includes all of the information provided on the SR and AE forms and a justification of why the event is serious, unexpected and has reasonable possibility of being caused by STOP-NAFLD study drug (see STOP-NAFLD SOP I, section 6.16).
- 3) A copy of your report to your IRB, if applicable

The Data Coordinating Center will submit a preliminary copy of the report to NIDDK (Sponsor) for further review within 3 business days. If NIDDK staff determines that an expedited IND Safety Report is required, a final report will be submitted to the FDA (within 15 days). The DSMB and Steering Committee will be notified of all serious adverse events requiring an expedited IND safety report within 7 days of keying the SR form. For more information, see STOP-NAFLD SOP I, section 6.16.

Followup report: A followup report should be filed (use this form) when the adverse event is resolved or if there has been a significant change in the patient's condition or in the physician's judgment about the event since the previous report was filed.

A. Center, patient and visit identification		5. Visit code:		
1. Center ID:		If report not associated with a visit, fill in "n."		
2. Patient ID:		6. Form & revision:	<u>s r 1</u>	
3. Patient code:		7. Study:	STOP-NAFLD 9	
4. Date of report:				
day	mon year			

2)

B. Participant information

8. Date randomized in STOP-NAFLD:

_		_
day	mon	year

9. Gender:

Male	(1)
Female	(2)

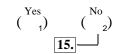
10. Age at time of adverse event:

C. Determination of an serious adverse report

11. Is there evidence to suggest a causal relationship between the STOP-NAFLD study drug and the adverse event:

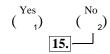
Definitely yes	(1)
Probably yes	(2)
Possibly yes	(3
Probably no	(4)
Definitely no	15. — 5)

12. Is this a serious adverse event:



If Yes, then select all the reasons that apply:

- **a.** Severity Grade 4 or 5:
- **b.** Required inpatient hospitalization or prolonged existing hospitalization: (1)
- c. Persistent or significant incapacity or substantial disruption of ability to conduct normal life functions: (1)
- d. Jeopardized patient and required medical or surgical intervention to prevent a serious event:
- e. Congenital anomaly or birth defect: (
- **13.** Is this an unexpected adverse event:



14. Reason the adverse event was unexpected:

observed

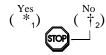
Not listed in the losartan potassium investigator brochure

Listed in the losartan potassium investigator's brochure, but not at the specificity or severity that has been

Listed in the losartan potassium investigator's brochure as anticipated from the pharmacological properties of the study drug, but is not specifically mentioned as occurring with previous

mentioned as occurring with previous experience of losartan potassium (

15. Did you select "Yes" for items 11, 12, and 13:



*NIDDK will determine if an expedited IND Safety Report will be submitted to the FDA within 15 calendar days.

†Use STOP-NAFLD AE form to report adverse events that are not serious, not associated with the STOP-NAFLD study drug, or are expected. Do not key this form.

D. Serious adverse event description

16. Is this the first report or a followup report for this serious adverse event:

First report (
Followup report (

17. Date of serious adverse event onset:

day mon year

18. Date serious adverse event was reported to clinical center:

day mon year

19. Describe the serious adverse event:

20.	Medications or supplements other than STOP-NAFLD study drug in use at the time of serious adverse event:	26. Current status of serious adverse event <i>(check only one):</i>		
	time of scrious adverse event.	Resolved (1)		
		Active (2)		
		Unknown (3)		
21.	Specify tests/treatments and comorbidities:	27. Date resolved:		
		day mon year		
		28. Additional comments on serious adverse event:		
	Was an unscheduled liver biopsy performed:			
	$\begin{pmatrix} \text{Yes} & \text{No} \\ \binom{*}{1} & \binom{*}{2} \end{pmatrix}$	E. Administrative information		
	*Attach a copy of the institutional pathology report to the SR form.	29. Study Physician PIN:		
23.	Did the serious adverse event result in significant sequelae:	30. Study Physician signature:		
	$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$	31. Clinical Coordinator PIN:		
	Specify:	32. Clinical Coordinator signature:		
		33. Date form reviewed:		
		day mon year		
24.	Short name for serious adverse event (short names for AEs are listed in the CTCAE v5.0 document available	Key this form and send the DCC within I business day:		
	at www.nashcrn.com; click on Studies and then click on STOP-NAFLD):	 (1) A copy of this SR form (2) A narrative description of the serious adverse event (3) A copy of your report to your IRB. 		
25.	Severity grade (severity grades are listed in the CTCAE v5.0 document available at www.nashcrn.com; click on Studies and then click on STOP-NAFLD):	We are asking for copies of these reports on serious adverse events so that we assure appropriate and timely study wide review. The serious adverse event report will be reviewed by Dr. Mariand Lazo, the Safety Officer, and NIDDK (Sponsor).		
	Grade 3 - Severe (1)			
	Grade 4 - Life threatening or			
	disabling (₂)			
	Grade 5 - Death $\binom{*}{3}$			

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

Transfer Notification

Purpose: To record a transfer from one center to another center.

When: Upon transferring to the enrolling center and prior to the first visit at the adopting center.

By whom: Clinical coordinator of each center (enrolling center: sections A-C, adopting center: sections D-E). Instruction: For enrolling center: When patient notifies enrolling center of upcoming transfer, the enrolling clinical coordinator should (1) complete Sections A-C of the Transfer Notification (TN Form), (2) send the TN form to the adopting center, with a copy of the most recently completed FH, LR, RD, and PE/PF forms, (3) send the labels for cryovials and slides and a copy of the visit window schedule to the adopting center. For adopting center: Prior to the patient coming to the adopting center, the adopting clinical coordinator should: (1) complete Sections D-E of the TN form, (2) Fax the TN form to the DCC (Fax: 410-955-0543). The DCC will key the form.

A. Enrolling center and patient identification		D. Adopting center, patient and visit identification	
1. Center ID:		14. Adopting center ID:	
2. Patient ID:		15. Patient ID (must be same as in Section A):	
3. Patient code:		16. Patient code: (must be same as in Section A):	
4. Date of notification of	of intent to transfer:		
day	mon year	17. Expected date of first follow-up visit at adopting center:	
5. Visit code:	<u> </u>	day mon year	
6. Form & revision:	<u>t</u> <u>n</u> <u>1</u>	18. Visit ID code for expected first follow-up visit at adopting center:	
7. Study:	STOP-NAFLD 9	_f	
3. Last follow-up visit in	formation	Reminder: Please follow your local IRB requirements regarding consent and HIPAA statements.	
8. Date of last follow-u	•	E. Adopting center administrative information	
day	mon year	19. Date form reviewed:	
9. Visit ID code of last visit:	completed follow-up _f	day mon year	
10. Have cryovial and sl		20. Clinical coordinator ID:	
to the adopting cente	er:	21. Clinical coordinator signature:	
	nd slide labels to the adopting age tracking service).		
C. Enrolling center adm	inistrative information	Fax form to the DCC. The DCC will key the TN form.	
11. Date form reviewed:			
day	mon year		
12. Clinical coordinator	ID:		
13. Clinical coordinator	signature:		