Keyed: ( )

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. Center, patient, and visit identification

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

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

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: **s** _____ _____

6. Form & revision: **a d 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the questionnaire completed:

Self-administered by patient (1)
→ **10.**
Interview in English (2)
Interview with translator (3)

9. Who was the respondent *(check all that apply)*:

a. Patient: (1)
b. Patient's mother or female guardian: (1)
c. Patient's father or male guardian: (1)
d. Other *(specify)*: (1)

_____
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
(0)	(1)	(2)	(3)	(4)

→ **22.**

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?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
(0)	(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?

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

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

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

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?

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

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

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

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

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

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

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

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

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

22. Today's date:

_____

Thank you for completing this questionnaire.

Keyed: ( )

STOP-NAFLD

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____
if report not associated with a visit, fill in "n"

6. Form & revision: a e 1

7. Study: STOP-NAFLD 9

B. Visit interval identification

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

Yes (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:

Yes (1) No (2)

11. ___

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:

Yes (1) No (2)

12. ___

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:

___ ___–___ ___ ___–___ ___
day mon year

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

a. Drug dispensing mixup: (1)
b. Medication related event: (1)
c. Study procedure related event: (1)
d. Severe allergic reaction: (1)
e. Drug interactions: (1)
f. Worsening of a co-morbid illness: (1)
g. Patient reported symptom of hepatotoxicity: (1)
h. Gastrointestinal symptoms: (1)
i. Diabetes: (1)
j. Pregnancy *(patient):* (*1)
k. Other *(specify):* (1)

_____

_____

**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: (1)
i. Dermatologic/skin: (1)
j. Endocrine/metabolic: (1)
k. Gastrointestinal/digestive: (1)
l. Lymphatic/blood: (1)
m. Musculoskeletal: (1)
n. Neurologic: (1)
o. Pulmonary/respiratory: (1)
p. Renal/genitourinary: (1)
q. Sexual/reproductive: (1)
r. Other *(specify):* (1)

_____
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):

(Yes 1) (No 2)

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

_____
_____

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:

(Yes 1) (No 2)

29.

b. Date randomized in STOP-NAFLD:

____ ____–____ ____ ____–____ ____
day mon year

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

(Yes 1) (No 2)

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/day

c. Have there been any treatment interruptions or restarts:

(Yes 1) (No 2)

Include stop/restart dates and reasons:

_____
_____
_____

24. 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 (5)

25. Is this a serious adverse event:

Yes (1) No (2)
26.

If Yes, then select all the reasons that apply:

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)
e. Congenital anomaly or birth defect: (1)

26. Is this an unexpected adverse event:

Yes (1) No (2)
28.

27. Reason the adverse event was unexpected:

Not listed in the losartan potassium investigator's brochure (1)
Listed in the losartan potassium investigator's brochure, but not at the specificity or severity that has been observed (2)
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 experience of losartan potassium (3)

28. Did you select "Yes" for items 24 (definitely, probably, or possibly), 25, and 26:

Yes (*1) No (2)

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

29. Current status of adverse event *(check only one):*

Resolved (1)
Active (2)
31.
Unknown (3)
31.

30. Date adverse event resolved:

___ ___–___ ___ ___–___ ___
day mon year

31. What action was taken:

_____
_____
_____
_____
_____
_____

32. Other comments on event:

_____
_____
_____
_____
_____
_____

E. Administrative information

33. Clinical Coordinator PIN: ___ ___ ___

34. Clinical Coordinator signature:

_____

35. Study Physician PIN: ___ ___ ___

36. Study Physician signature:

_____

37. Date form reviewed:

___ ___–___ ___ ___–___ ___
day mon year

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

STOP-NAFLD

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 ⚠C is checked for an item, use caution. If the physician agrees with the diagnosis, the patient is ineligible for STOP-NAFLD. If ⊘PMH 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: s ____ ____

6. Form & revision: b h 1

7. Study: STOP-NAFLD 9

B. NAFLD history

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):*

Yes (*1) No (2)

10.

**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:

Yes (*1) No (2)

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:

Yes (1) No (2)

18.

13. Have you ever smoked tobacco cigarettes:

Never (1)

18.

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):*

Yes (1) No (2)

18.

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:

Yes (1) No (2) → 25.

19. Menarche history

a. Has menarche occurred:

Yes (1) No (2) → 25.

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:

Yes (1) No (2) → 25.

22. Is the patient currently pregnant:

Yes (1) → Elig No (2)

23. Is the patient currently breastfeeding:

Yes (*1) → C No (2)

**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:

Yes (1) → Elig No (2)

E. Medical history *(⚠C 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: (*1)

b. Diabetes type 2: (*1)

**If HbA1c is ≥ 9.5%, patient is ineligible.*

c. Hepatitis B: (1) → ⚠C

d. Hepatitis C: (1) → ⚠C

e. Autoimmune hepatitis: (1) → ⚠C

f. Autoimmune cholestatic liver disorder (PBC or PSC): (1) → ⚠C

g. Wilson's disease: (1) → ⚠C

h. Alpha-1-antitrypsin (A1AT) deficiency: (1) → ⚠C

i. Hemochromatosis or iron overload: (1) → ⚠C

j. Drug induced liver disease: (1) → ⚠C

k. Ascites: (1) → ⚠C

l. Gilbert's syndrome: (1)

m. Esophageal or gastric varices on endoscopy: (1) → ⚠C

n. Bleeding from varices: (1) → ⚠C

o. Gastrointestinal ulcers or other gastrointestinal bleeding: (1)

p. Biliary diversion: (1)

q. Metabolic acidosis: (1)

r. Edema: (1)

s. Hepatic encephalopathy: (1)

t. Any other evidence of chronic liver disease: (1)

u. Short bowel syndrome: (1)

v. Hemophilia *(bleeding disorder):* (1)

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

x. Endocrine disease *(hormonal abnormality):* (1)

y. Asthma: (1)

z. Hepatocellular carcinoma: (1)

aa. Other malignancy *(cancer):* (1)

ab. Human immunodeficiency virus (HIV): (1)

ac. Peripheral neuropathy: (1)

ad. Seizure disorder or epilepsy: (1)

ae. Drug allergies: (1)

af. Hypothyroidism: (1)

ag. Stage 2 hypertension: (1)

ah. Hypotension or orthostatic hypotension: (1)

ai. Cerebrovascular disease: (1)

aj. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

ak. Pancreatitis: (1)

al. Cholelithiasis: (1)

am. Coronary artery disease: (1)

an. Elevated uric acid such as gout: (1)

ao. Kidney disease: (1)

ap. Polycystic ovary syndrome: (1)

aq. Sleep apnea: (1)

ar. Dermatologic disorders: (1)

as. Myopathy: (1)

at. Myositis: (1)

au. Major depression: (1)

av. Schizophrenia: (1)

aw. Bipolar disorder: (1)

ax. Obsessive compulsive disorder: (1)

ay. Severe anxiety or personality disorder: (1)

az. Substance abuse: (1)

ba. None of the above: (1)

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

a. Stapling or banding of the stomach: (1)

b. Jejunoileal *(or other intestinal)* bypass: (1)

c. Biliopancreatic diversion: (1)

d. Other bariatric surgery *(specify):* (1)

_____

e. None of the above: (1)

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

Yes (1) No (2)

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

Yes (1) No (2)

29. Organ, limb, or bone marrow transplant

a. Has the patient ever received a liver transplant:

(Yes 1) (No 2)

C

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

(Yes 1) (No 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): (1)
d. Doxycycline (Monodox): (1)
e. Isonicotinylhydrazine (INH, Isoniazid, Tubizid): (1)
f. Isotretinoin (Accutane, Amnesteem, Clarvis, or Sotret): (1)
g. Methotrexate (Rheumatrex): (1)
h. Minocycline (Dynacin, Minocin): (1)
i. Oxytetracycline (Terramycin): (1)
j. Tetracycline (Achromycin): (1)
k. Valproate sodium (Depacon): (1)
l. Valproic acid (Depakene): (1)
m. Other known hepatotoxin *(specify):* (1)

_____

n. None of the above: (1)

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

(Yes * 1) (No 2)

C

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

_____

k. None of the above: (1)

33. Were any of the items 32a-j checked:

(Yes * 1) (No 2)

C

**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:

(Yes 1) (No 2)

Elig

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

a. Boldenone undecylenate (Equipoise): (1)
b. Fluoxymesterone (Android-F, Halotestin): (1)
c. Methandrostenolone (Dianabol): (1)
d. Methyltestosterone (Android): (1)
e. Nandrolone (Deca-Durabolin, Durabolin, Hybolin Decanoate, Kabolin): (1)
f. Oxandrolone (Oxandrin): (1)
g. Oxymetholone (Anadrol): (1)
h. Stanzolol (Winstrol): (1)
i. Tamoxifen (Nolvadex): (1)
j. Testosterone (Depo-Testosterone): (1)
k. Other, *(specify):* (1)

_____

l. None of the above: (1)

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

Yes (*1) No (2)
C

**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:

Yes (1) No (2)
C

G. Use of antidiabetic drugs

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

Yes (1) No (2)
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): (*1)
w. Miglitol (Glycet): (1)
x. Nateglinide (Starlix): (1)
y. Pioglitazone (Actos): (1)
z. Pioglitazone/Glimepiride (Duetact) (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.*

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) (*1)
ag. Saxagliptin (Onglyza) (1)
ah. Saxagliptin/Metformin (Kombiglyze XR) (*1)
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:

Yes (1) No (2)

40.

(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 (1) No (2)

41.

(If yes, check all that apply)

a. Vitamin A: (1)
b. Vitamin B (any type): (1)
c. Vitamin C: (1)
d. Vitamin D: (1)
e. Vitamin E: (*1)

C

f. Multivitamin: (1)
g. Potassium (any form): (†1)

C

h. Other, *(specify):* (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 (1) No (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 (1) No (2)

43. ____

(If yes, check all that apply)

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

_____

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 (1) No (2)

45. ____

(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)

_____

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

(Yes 1) Elig (No 2)

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

(Yes 1) (No 2) → **46.**

(If yes, check all that apply)

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

_____

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

_____

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

(Yes * 1) (No 2) → C

(If yes, check all that 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)
ag. Other, *(specify):* (1)

_____

** Current treatment with any antihypertensive medication is exclusionary.*

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

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

49. ____

(If yes, check all that apply)

a. Albuterol: ( ) (1)

b. Beclomethasone dipropionate (Beclovent, Vanceril): ( ) (1)

c. Budesonide (Pulmicort, Rhinocort): ( ) (1)

d. Fluticasone propionate (Flonase, Flovent): ( ) (1)

e. Loratadine (Claritin): ( ) (1)

f. Mometasone furoate (Nasonex): ( ) (1)

g. Triamcinolone acetonide (Azmacort, Nasacort): ( ) (1)

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

_____

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

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

51. ____

(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)

j. Sertraline (Zoloft): ( ) (1)

k. Other (specify): ( ) (1)

_____

50. Is the patient currently being treated with lithium:

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

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

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

53. ___

(If yes, check all that apply)

a. Levonorgestrel (Norplant): (1)
b. Levothyroxine (Levoxyl, Synthroid): (1)
c. Liothyronine (Cytomel): (1)
d. Oral contraceptives: (1)
e. Penicillamine (Cuprimine, Depen): (1)
f. Trientine hydrochloride (Syprine): (1)
g. Other, *(specify):* (1)

_____

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

_____

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

_____

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

_____

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

_____

53. Has the patient participated in an IND trial in the past 150 days:

Yes (1) No (2)

(1) → Elig

J. Administrative information

54. Study Physician PIN: ___ ___ ___

55. Study Physician signature:

_____

56. Clinical Coordinator PIN: ___ ___ ___

57. Clinical Coordinator signature:

_____

58. Date form reviewed:

___ ___ – ___ ___ ___ – ___ ___
day mon year

Keyed: ( )

STOP-NAFLD

BL - Blood Pressure Log Documentation

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: b 1 2

7. Study: STOP-NAFLD 9

B. Blood pressure log information

8. Blood pressure cuff given to patient:

Arm (1)

Wrist (2)

9. Was the blood pressure log returned or was a photo of the log obtained:

Yes (1) No (* 2)

14.

** Remind patient to bring log to next visit.*

a. Date log returned:

____ ____–____ ____ ____–____ ____
day mon year

10. Number of days blood pressure recorded:

____ ____
(00-14)

11. Number of days with elevated blood pressure (systolic BP greater than 140 mm/Hg or diastolic BP greater than 90 mm/Hg):

____ ____ *
(00-14)

**If one or more, email this form and the Blood Pressure Log to Pat Belt at the DCC (pbelt@jhu.edu).*

12. Number of days with low blood pressure (systolic BP less than 90 mm/Hg or diastolic BP less than 60 mm/Hg):

____ ____ *
(00-14)

**If one or more, email this form and the Blood Pressure Log to Pat Belt at the DCC (pbelt@jhu.edu).*

13. Were any adverse events related to blood pressure reported:

Yes (1) No (2)

C. Administrative information

14. Clinical Coordinator PIN: ____ ____ ____

15. Clinical Coordinator signature:

_____

16. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Keyed: ( )

STOP-NAFLD

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 **one** 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 **two** 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 visit identification

1. Center code: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: b p 1

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 (1) No (2)

**A 12-hour fast is preferred, but will accept non-fasting samples.*

a. Was blood collected for the NIDDK Biosample Repository:

Yes (1)

Yes, previously collected for NAFLD Database 2 (*2)

No, *(specify):* (†3)

23. ____

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 blood draw

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____ : ____ ____ (1) am (2) pm
hour minute

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

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

STOP-NAFLD Form BP,
BP Plasma.
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:

____ ____ : ____ ____ (1) am (2) pm
hour minute

c. Time of serum separation:

____ ____ : ____ ____ (1) am (2) pm
hour minute

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:

_____
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:

____ ____–____ ____ ____–____ ____
day mon year

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

STOP-NAFLD

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

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date of visit :

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: b q 1

7. Study: STOP-NAFLD 9

C. Administrative information

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

24. Clinical Coordinator PIN: ____ ____ ____

25. Clinical Coordinator signature:

_____

26. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

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.

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___ ___

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

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

2) Indicate the approximate amount of beverage you drank each time, for example, you drank 1 cup of water each time, circle response "2" under the column labeled "8 fl oz (1 cup)" under "how much each time.

3) Do not count beverages used in cooking or other preparations, such as milk in cereal.

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

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

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

Keyed: ( )

STOP-NAFLD

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 μg) 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.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: c g 1

7. Study: STOP-NAFLD 9

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:

Yes (1) No (2)

10. ____

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):*

Yes (1) No (2)

15. ____

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 (1)

12. ____

No, *(specify):* (2)

_____
specify

15. ____

12. Date and time of blood draw

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Time:

____ ____ : ____ ____ (1) am (2) pm
hour minute

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

Keyed: ( )

STOP-NAFLD

CO - Closeout Form

Purpose: To close out a patient's participation in STOP-NAFLD and document the patient's consent to join or re-enter 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.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: f 3 6

6. Form & revision: c o 1

7. Study: STOP-NAFLD 9

B. Database participation

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

Yes (1) No (2)

11.

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

Yes (1) No (*2) STOP

** Patient/parent must sign the informed consent*

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

Yes (*1) No (+2)

** 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:

____ ____–____ ____ ____–____ ____
day mon year

Central Histology Review

Purpose: Record results of the NASH CRN Pathology Committee review of liver biopsy slides archived at the Histology Review Center.
When: Quarterly after the start of patient enrollment or more often as determined by the Pathology Committee.
By whom: Data Coordinating Center staff.
Instructions: Upon review of the liver biopsy slides by the NASH CRN Pathology Committee, the designated Data Coordinating Center staff member should complete the CR form. The CR form will be keyed by the Data Coordinating Center personnel.

A. Clinic, patient and visit identification

__ __ __ __ 1. Center ID

__ __ __ __ 2. Patient ID

__ __ __ 3. Patient code

__ __ / __ __ __ / __ __ 4. Date of central reading

__ __ __ __ 5. Visit code

c r 3 6. Form and revision

__ 7. Study: **6**=Database 2; **9**=STOP-NAFLD

__ __ / __ __ __ / __ __ 8. Date of biopsy

B. Slide sequence number

9. Sequence number for

__ __ . . . a. H & E stained slide

__ __ . . . b. Masson's trichrome stained slide

__ __ . . . c. Iron stained slide

C. Adequacy of biopsy

__ __ 10. Biopsy length (mm)

__ 11. Tissue adequate: **0**=No ➜ Request original slides from submitting clinic; **1**=Yes

_____ 12. Followup with clinic (*Specify*):

D. Histology

_____ *Patient ID*

H & E stain

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

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

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

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

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

14. Inflammation

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

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

15. Liver cell injury

_____ . . . a. Ballooning: **0**=None ➜ **GOTO Item 15d**; **1**=Few; **2**=Many

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

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

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

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

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

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

19. **Masson's trichrome stain**

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

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

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

20. **Iron stain**

_____ . . . a. Hepatocellular iron grade: **0**=Absent or barely discernible, 40x ➜ **GOTO item 20c**; **1**=Barely 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
  - Make sure that you are comfortable and relaxed.
  - Obtain blood pressure measurements on your RIGHT arm every day for 14 days.
  - Roll up the sleeve on your right arm or remove any tight-sleeved clothing.
  - 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	

TO BE COMPLETED BY CLINIC STAFF:

Study doctor name (print): _____ **Telephone #:** _____

Study Coordinator name (print): _____

Keyed: ( )

STOP-NAFLD

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 identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form is initiated *(date of notice):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____ ____

6. Form & revision: d r 1

7. Study: STOP-NAFLD 9

B. Death information

8. Date of death:

____ ____–____ ____ ____–____ ____
day mon year

9. Source of death report *(check all that apply):*

a. Patient's family: (1)
b. Friend: (1)
c. Other caregiver: (1)
d. Health care provider or NASH CRN staff: (1)
e. Newspaper: (1)
f. Funeral parlor/home: (1)
g. Medical record: (1)
h. Medical examiner: (1)
i. Coroner: (1)
j. National Death Index (NDI): (1)
k. Social Security Death Master File (SSDMF): (1)
l. Other *(specify):* (1)

_____
other source

_____
other source

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:

_____
city/state/country

11. Has a death certificate been obtained:

(Yes 1) (No 2)

If no, please obtain or explain 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) **13.** ___

Cardiovascular disease (02) **14.** ___

Liver disease (03) **15.** ___

Malignancy (cancer) (04) **16.** ___

Gastrointestinal (GI) disease (05) **17.** ___

Pulmonary (lung) disease (06) **18.** ___

Pneumonia (07) **19.** ___

Complication of diabetes (08) **19.** ___

Accident (09) **19.** ___

Suicide (10) **19.** ___

Homicide (11) **19.** ___

Kidney disease or renal failure (12) **19.** ___

Sepsis, staph or other infection (13) **19.** ___

Multi-organ failure (14) **19.** ___

Other *(specify):* (15) **19.** ___

_____

Unknown (16) **19.** ___

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

Definite fatal myocardial infarction (MI) or heart attack (1)

Defined as: *1. Death within 28 days of hospital admission,* ***OR***
2. Postmortem findings consistent with MI within 28 days of hospital admission, ***OR***
3. 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***
4. Autopsy evidence of recent coronary occlusion or MI < 28 days old.

Probable fatal MI (2)

Defined as: *1. Death within 28 days of hospital admission in cases defined in probable MI cases,* ***OR***
2. Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or not diagnostic).

Definite fatal CHD (3)

Defined as: *1. A history of CHD and/or documented cardiac pain within 72 hours before death and no evidence of a noncoronary cause of death,* ***OR***
2. Autopsy evidence of chronic CHD, including coronary atherosclerosis and myocardial scarring.

Go to 19.

14. CAUSE OF DEATH: Cardiovascular (CVD) disease subclassification ***(check only one)****:*

Congestive heart failure (CHF) (1)

Defined as: Death due to clinical, radiologic or postmortem evidence of CHF without clinical or postmortem evidence of an acute ischemic event (cardiogenic shock included).

Documented arrhythmia (2)

Defined as: Death due to brady- or tachy- arrhythmias not associated with an acute ischemic event.

Cerebrovascular (stroke) (3)

Defined as: Death due to stroke occurring within 7 days of signs and symptoms of stroke or during admission for stroke.

Other cardiovascular (4)

Defined as: Death due to other known vascular diseases including abdominal aortic aneurysm rupture.

Specify: _____

Go to 19.

15. CAUSE OF DEATH: Liver disease subclassification ***(check only one)****:*

Nonalcoholic fatty liver disease (NAFLD)	(1)
Chronic hepatitis C	(2)
Acute liver failure	(3)
Other *(specify):*	(4)

_____

19. ____

16. CAUSE OF DEATH: Malignancy (cancer) subclassification ***(check only one)****:*

Breast cancer	(01)
Colon cancer	(02)
Endometrial/Uterine cancer	(03)
Esophageal cancer	(04)
Hepatocellular carcinoma (HCC)* * *Complete and key the HC form.*	(05)
Ovarian cancer	(06)
Pancreatic cancer	(07)
Prostate cancer	(08)
Rectal cancer	(09)
Other known cancer or malignant tumor *(specify):*	(10)

_____

Unknown cancer site	(11)

19. ____

17. CAUSE OF DEATH: Gastrointestinal 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)

_____

19. ____

18. CAUSE OF DEATH: Pulmonary (lung) subclassification ***(check only one)****:*

Asthma	(1)
Acute respiratory failure	(2)
Interstitial lung disease (ILD)	(3)
Other *(specify):*	(4)

_____

19. Contributing causes of death ***(check all that apply)****:*

a. Coronary heart disease (CHD) *(specify):*	(1)

_____

b. Cerebrovascular disease (stroke):	(1)
c. Congestive heart failure (CHF):	(1)
d. Documented arrhythmia, not associated with MI:	(1)
e. Other cardiovascular disease *(specify):*	(1)

_____

f. Diabetes Type 1:	(1)
g. Diabetes Type 2:	(1)
h. Liver disease *(specify):*	(1)

_____

i. Hepatocellular (liver) carcinoma (HCC)*: * *Complete and key the HC form.*	(1)
j. Other malignancy (cancer) *(specify):*	(1)

_____

k. Gastrointestinal (GI) disease *(specify):*	(1)

_____

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)
r. None:	(1)

20. Was this a procedure-related death:

(Yes 1) (No 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 (3)

23. Documentation available for future 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)

g. Coroner's report: (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 Physician PIN: ____ ____ ____

26. Study Physician signature:

_____

27. Clinical Coordinator PIN: ____ ____ ____

28. Clinical Coordinator signature:

_____

29. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

Narrative - do not key:

Keyed: ( )

STOP-NAFLD

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.

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: 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 since the last visit:

Yes (*1) No (2)

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

C. Use of effective birth control

11. Is the patient female:

Yes (1) No (2)
14.

12. Has menarche occurred:

Yes (1) No (2)
14.

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

Yes (1)
No (*2)
** 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:

Yes (1) No (2)
21.

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 (4)

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 (4)

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 (4)

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 (1) 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: (1)
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: (1)
l. Gilbert's syndrome: (1)
m. Esophageal or gastric varices on endoscopy: (1)
n. Bleeding from varices: (1)
o. Gastrointestinal ulcers or other gastrointestinal bleeding: (1)
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: (1)
v. Hemophilia *(bleeding disorder):* (1)
w. Systemic autoimmune disorder such as rheumatoid arthritis or systemic lupus: (1)
x. Endocrine disease *(hormonal abnormality):* (1)
y. Asthma: (1)
z. Hepatocellular carcinoma: (1)
aa. Other malignancy *(cancer):* (1)
ab. Human immunodeficiency virus (HIV): (1)
ac. Peripheral neuropathy: (1)
ad. Active seizure disorder or epilepsy: (1)
ae. Drug allergies: (1)

af. Hypothyroidism: (1)
ag. Stage 2 hypertension: (1)
ah. Hypotension or orthostatic hypotension (1)
ai. Cerebrovascular disease: (1)
aj. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)
ak. Pancreatitis: (1)
al. Cholelithiasis: (1)
am. Coronary artery disease: (1)
an. Elevated uric acid such as gout: (1)
ao. Kidney disease: (1)
ap. Polycystic ovary syndrome: (1)
aq. Sleep apnea: (1)
ar. Dermatologic disorders: (1)
as. Myopathy: (1)
at. Myositis: (1)
au. Major depression: (1)
av. Schizophrenia: (1)
aw. Bipolar disorder: (1)
ax. Obsessive compulsive disorder: (1)
ay. Severe anxiety or personality disorder: (1)
az. Substance abuse: (1)
ba. None of the above: (1)

22. Since the last visit, has the patient had bariatric surgery *(check all that apply)*

a. Stapling or banding of the stomach: (1)
b. Jejunoileal *(or other intestinal)* bypass: (1)
c. Biliopancreatic diversion: (1)
d. Other bariatric surgery *(specify):* (1)

_____

e. None of the above: (1)

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

Yes (1) No (2)

G. Drugs historically associated with NAFLD

24. Since the last visit, has the patient used any of the following:

Yes (1) No (2)

25. ____

(If yes, check all that apply)

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

_____

25. Since the last visit, has the patient taken any systemic glucocorticoids:

Yes (1) No (2)

26. ____

(If yes, check all that apply)

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

_____

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

Yes (1) No (2)

27. ____

(If yes, check all that apply)

a. Boldenone undecylenate (Equipoise): (1)

b. Fluoxymesterone (Android-F, Halotestin): (1)

c. Methandrostenolone (Dianabol): (1)

d. Methyltestosterone (Android): (1)

e. Nandrolone (Deca-Durabolin, Durabolin, Hybolin Decanoate, Kabolin): (1)

f. Oxandrolone (Oxandrin): (1)

g. Oxymetholone (Anadrol): (1)

h. Stanzolol (Winstrol): (1)

i. Tamoxifen (Nolvadex): (1)

j. Testosterone (Depo-Testosterone): (1)

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

_____

H. Use of antidiabetic drugs

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

Yes (1) No (2)

28. ____

(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. Exanitide (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): (1)

w. Miglitol (Glycet): (1)

x. Nateglinide (Starlix): (1)

y. Pioglitazone (Actos): (1)

z. Pioglitazone/Glimepiride (Duetact) (1)

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) (1)
ag. Saxagliptin (Onglyza) (1)
ah. Saxagliptin/Metformin (Kombiglyze XR) (1)
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)

_____

I. Use of supplements, vitamins, and other drugs

28. Since the last visit, has the patient taken any of the following supplements/drugs:

Yes (1) No (2)

29. ____

(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. Vitamin E: (1)
h. Vitamin A: (1)
i. Vitamin B (any type): (1)
j. Vitamin C: (1)
k. Vitamin D: (1)
l. Multivitamin: (1)
m. Potassium (any form): (* 1)
n. Other *(specify):* (1)

_____
specify

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

J. Use of statins, fibrates, and antiobesity drugs

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

Yes (1) No (2)

30. ____

(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)

_____

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

Yes (1) No (2)

31.

(If yes, check all that apply)

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)
i. Other, *(specify):* (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 (1) No (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)
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)

_____

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

Yes (* 1) No (2)

33.

(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 (*1) No (2)

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): (1)
w. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)
x. Metoprolol (Lopressor): (1)
y. Nifedipine (Adalat, Procardia): (1)
z. Olmesartan (Benicar): (1)
aa. Perhexiline 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)

_____

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

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

Yes (1) No (2)

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)
j. Sertraline (Zoloft): (1)
k. Other (specify): (1)

_____

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

Yes (1) No (2)

36. ____

(If yes, check all that apply)

a. Levonorgestrel (Norplant): (1)
b. Levothyroxine (Levoxyl, Synthroid): (1)
c. Liothyronine (Cytomel): (1)
d. Oral contraceptives: (1)
e. Penicillamine (Cuprimine, Depen): (1)
f. Trientine hydrochloride (Syprine): (1)
g. Other, *(specify):* (1)

_____

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

_____

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

_____

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

_____

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

_____

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

Keyed: ( )

STOP-NAFLD

HF - Liver Biopsy Histology Findings

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 Elig is checked for any item, the patient is not eligible for STOP-NAFLD and the form should not be keyed. If C 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.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s ____ ____

6. Form & revision: h f 1

7. Study: STOP-NAFLD 9

B. Biopsy information

8. Date this biopsy was performed *(obtained from surgical pathology report):*

____ ____–____ ____ ____–____ ____
day mon year

9. Has the biopsy been reviewed centrally for DB2:

Yes (*1) No (2)

** Contact the DCC to obtain the Central Review evaluation and transcribe the data in items 11-20.*

10. What slides are to be used in this evaluation *(check all that apply)*

a. H & E: (1)

b. Masson's trichrome: (1)

c. Iron: (1)

11. Biopsy length: ____ ____ mm

C. NASH evaluation (use H & E and Masson's trichrome slides only)

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

a. Grade:

< 5% (0) Elig ____

5-33% (1)

34-66% (2)

> 66% (3)

b. Location:

Zone 3 (0)

Zone 1 (1)

Azonal (2)

Panacinar (3)

13. Fibrosis stage *(Masson's trichrome stain)*

0: None (0)

1a: Zone 3, perisinusoidal (requires trichome) (1)

1b: Zone 3, perisinusoidal (easily seen on H & E) (2)

1c: Portal/periportal only (3)

2: Zone 3 and periportal, any combination (4)

3: Bridging (5)

4: Cirrhosis (6) Elig ____

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)
> 4 / 20x mag (3)

b. Amount of portal, chronic inflammation:

None to minimal (0)
Mild (1)
More than mild (2)

15. Hepatocellular ballooning:

None (0)
Few (1)
Many (2)

16. Is steatohepatitis present:

Not NAFLD (0) Elig

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

D. Exclusion of other liver disease

17. Is there evidence of primary biliary cirrhosis:

Yes (* 1) C No (2)

** Caution: Primary biliary cirrhosis is exclusionary*

18. Is there evidence of Wilson's disease:

Yes (* 1) C No (2)

** Caution: Wilson's disease is exclusionary*

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

a. Bile duct loss/infiltration/sclerosis: (* 1) C

b. Florid duct lesions: (1)
c. Cholate stasis: (1)
d. Copper deposition: (1)
e. Other *(specify):* (1)

_____

f. None: (1)

** 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: (1)
b. Inflammation suggestive of AIH, HCV: (* 1)
c. Pigment suggestive of HH: (* 1)
d. Globules suggestive of A1AT: (* 1)
e. Hepatocellular changes suggestive of HBV: (* 1)
f. Granulomas suggestive of sarcoid, PBC, infection: (* 1)
g. Other *(specify):* (1)

_____

h. None: (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) ____ 0-8

22. Is item 21 (NAS) 2 or less: Yes (1) No (2)

F. Other comments

23. Other comments:

_____
_____
_____
_____
_____

G. Administrative information

24. Study Pathologist PIN: ____ ____ ____
(Enter "CR" if Central Review scoring was used):

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of reading:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____ ____

6. Form & revision: h w 2

B. Biopsy information

7. Date this biopsy was performed *(obtained from surgical pathology report):*

____ ____–____ ____ ____–____ ____
day mon year

8. What slides are to be used in this evaluation *(check all that apply)*

a. H & E: (1)

b. Masson's trichrome: (1)

c. Iron: (1)

9. Biopsy length: ____ ____ mm

C. NAFLD evaluation (use H & E and Masson's trichrome slides only)

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

a. Grade:

< 5% (0)
5-33% (1)
34-66% (2)
> 66% (3)

b. Location:

Zone 3 (0)
Zone 1 (1)
Azonal (2)
Panacinar (3)

11. Fibrosis stage *(Masson's trichrome stain)*

0: None (0)
1a: Zone 3, perisinusoidal (requires trichome) (1)
1b: Zone 3, perisinusoidal (easily seen on H&E) (2)
1c: Portal/periportal only (3)
2: Zone 3 and periportal, any combination (4)
3: Bridging (5)
4: Cirrhosis (6)

12. Inflammation

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 (3)

b. Amount of portal, chronic inflammation:

None to minimal (0)
Mild (1)
More than mild (2)

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 (4)

15. NAFLD activity score (NAS) *(sum of items 10a, 12a, and 13):* ____ 0-8

D. Exclusion of other liver disease

16. Is there evidence of primary biliary cirrhosis:

(Yes 1) (No 2)

17. Is there evidence of Wilson's disease:

(Yes 1) (No 2)

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

a. Bile duct loss/infiltration/sclerosis: (1)
b. Florid duct lesions: (1)
c. Cholate stasis: (1)
d. Copper deposition: (1)
e. Other *(specify):* (1)

_____

f. None: (1)

19. Features 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)
d. Globules suggestive of A1AT: (1)
e. Hepatocellular changes suggestive of HBV: (1)
f. Granulomas suggestive of sarcoid, PBC, infection: (1)
g. Other *(specify):* (1)

_____

h. None: (1)

E. Other comments

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 (NAV) is checked for any item, then the form should not be keyed.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: l r 1

7. Study: STOP-NAFLD 9

B. Hematology

Required at visits s, f12, f24, and f36.

8. Is hemotology required at this visit:

(Yes 1) (No 2)

15. ____

9. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
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).

10. Hemoglobin: ____ ____ • ____
g/dL

11. Hematocrit: ____ ____ • ____
%

12. Mean corpuscular volume (MCV):

____ ____ ____
fL

13. White blood cell values

a. White blood cell count (WBC):

____ ____ • ____
10^3 cells/ µL or 10^9 cells/L

b. Red blood cell count (RBC):

____ ____ • ____ ____
mill cells/µL

c. Neutrophils: ____ ____ ____ ____
cells/ µL

d. Lymphocytes: ____ ____ ____ ____
cells/ µL

e. Monocytes: ____ ____ ____ ____
cells/ µL

f. Eosinophils: ____ ____ ____ ____
cells/ µL

g. Basophils: ____ ____ ____ ____
cells/ µL

14. Platelet count:

____ ____ ____,____ ____ ____
cells/mm^3

If platelets < 100,000 cells/mm^3 (mm^3 = µL) at screening, patient is ineligible.

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: ____ ____ ____ mEq/L

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-NAFLD/STOPNAFLD.htm); enter 75.0 if eGFR is ≥ 75mL/mim/1.73m^2;if eGFR <60mL/mim/1.73m^2 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:

Yes (1) No (2)

29. ____

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): ____ ____ • ____ sec

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:

Yes (1) No (2)

33. ____

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

____ ____–____ ____ ____–____ ____
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).

31. Uric acid: ____ ____ • ____ mg/dL

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):

____ ____ • ____
mg/L

F. Hemoglobin A1c

Required at visits s, f12, and f24.

33. Is HbA1c required at this visit:

(Yes 1) (No 2)
36.

34. Date of blood draw for HbA1c:

____ ____–____ ____ ____–____ ____
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).

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:

____ ____–____ ____ ____–____ ____
day mon year

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): ____ ____ • ____
mg/dL

a. Upper limit of normal: ____ • ____
mg/dL

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: ____ ____
U/L

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: ____ ____
U/L

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:

(Yes 1) (No 2)
47.

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

(Yes 1) (No * 2)

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

46. Date of blood draw for fasting lipid profile:

____ ____–____ ____ ____–____ ____
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. Triglycerides: ____ ____ ____ ____ mg/dL

b. Total cholesterol: ____ ____ ____ mg/dL

c. HDL cholesterol level: ____ ____ ____ mg/dL

d. LDL cholesterol level*: ____ ____ ____ 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:

Yes (1) No (2)

50.

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

Yes (1) No (*2)

50.

**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 (1)

Serum (2)

c. Insulin: ____ ____ ____ • ____ µU/mL

d. Was insulin obtained using plasma or serum:

Plasma (1)

Serum (2)

J. Pregnancy test

Required at all study visits, if applicable.

50. Is pregnancy test applicable:

Yes (1) No (2)

53.

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

____ ____–____ ____ ____–____ ____
day 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 (1)

Negative (2)

K. Eligibility check

53. Is this the screening visit:

Yes (1) No (2)

55.

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:

Yes (1) No (2)

→ Elig

L. Administrative information

55. Study Physician PIN: ____ ____ ____

56. Study Physician signature:

_____

57. Clinical Coordinator PIN: ____ ____ ____

58. Clinical Coordinator signature:

_____

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 EHG is checked for any item the patient is not eligible for the STOP-NAFLD trial. If C 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ – ____ ____ ____ ____ – ____ ____
day mon year

5. Visit code: s ____ ____

6. Form & revision: l s 1

7. Study: STOP-NAFLD 9

B. Screening etiologic tests

8. Date of blood draw for serological assays to exclude viral causes of chronic liver disease:

____ – ____ ____ ____ ____ – ____ ____
day mon year

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

a. Hepatitis B surface antigen (HBsAg):
Positive (1) EHG
Negative (2)

b. Hepatitis C antibody (anti-HCV) *(indicate result as negative if EIA is positive but RIBA is negative):*
Positive (1) EHG
Negative (2)

c. Hepatitis C virus RNA (HCV RNA):
Positive (1) EHG
Negative (2)
Not available (3)

C. Autoantibody studies

9. Date of blood draw for autoantibody tests:

____–____ ____ ____ ____–____ ____
day mon year

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

Yes (* 1) No (2)
C

** 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 (* 1)
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 greater than 5 years prior to screening.

15. Anti-mitochondrial antibody (AMA):

Positive (* 1)
Negative (2)
17.
Not available (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

Yes (* 1) No (2)
C

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

D. Ceruloplasmin

17. Date of blood draw for ceruloplasmin:

____–____ ____ ____ ____–____ ____
day mon year

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

18. Ceruloplasmin ____ ____ • ____
mg/dL

a. Lower limit of normal: ____ ____ • ____
mg/dL

b. Is ceruloplasmin below the lower limit of normal:

Yes (* 1) No (2)
C

** 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: ____ ____ ____ mg/dL

21. A1AT phenotype* *(check only one):*

MM	(1)
MS	(2)
MZ	(3)
SZ	(4)
ZZ	(5)
Other *(specify):*	(6)

_____
specify

Not available (7)

**If the phenotype result includes numbers, the numbers should be disregarded when reporting the result (e.g., M1M2 should be reported as MM).*

22. Is A1AT deficiency the primary cause of this patient's liver disease *(physician assessment):*

Yes (1) No (2)
Elig

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: ____ ____ ____ µg/dL

c. Ferritin: ____ ____ ____ ____ ng/mL

24. Is hepatic iron index available:

Yes (1) No (2)
26.

25. Hepatic iron index: ____ • ____ µmol/g/year

G. Other screening blood tests

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

Yes (1) No (2)
29.

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

____ – ____ ____ ____ ____ – ____ ____
day mon year

28. Thyroid stimulating hormone: ____ ____ • ____ ____ µU/mL

H. Administrative information

29. Study Physician PIN: ____ ____ ____

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____ ____ ____ ____ ____
day mon year

5. Visit code: f ____ ____

6. Form & revision: m v 1

7. Study: STOP-NAFLD 9

B. Reason for completion of this form

8. Was the entire visit missed:

(Yes 1) (No 2)

11.

C. Missed visit information

9. Reason for missed visit *(check all that apply)*

a. Patient was ill: (1)

b. Patient was temporarily away from area: (1)

c. Patient refused to return: (1)

d. Patient has permanently moved from the area: (1)

e. Unable to contact patient: (1)

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

_____
specify

10. Steps taken to avoid missing the visit *(check all that apply)*

a. Telephoned patient: (1)

b. Mailed reminder card: (1)

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

_____
specify

14.

D. Missed form information

11. Check form(s) not completed *(check all that apply)*

a. Blood Processing for Plasma and Serum (BP): (1)

b. Follow-up Medical History (FH): (1)

c. Beverage intake questionnaire (BQ): (1)

d. Laboratory Results - Tests Done During Screening and Follow-up (LR): (1)

e. Physical Examination (PE): (1)

f. Focused Physical Examination (PF): (1)

g. Parent Report for Teens (13-17) (PQ): (1)

h. Pediatric QOL: Parent Report for Child (8-12) (PR): (1)

i. Pediatric QOL: Child Report (PW): (1)

j. Pediatric QOL: Teen Report (PY): (1)

k. Study Drug Dispensing and Return (RD): (1)

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

_____
specify

12. Reason form(s) not completed *(check all that apply)*

a. Patient was ill: (1)

b. Patient/parent refused procedure: (1)

c. Procedure forgotten: (1)

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

_____
specify

13. Attempts made to complete form(s)
(check all that apply)

a. Attempted to reschedule procedure: (1)

b. Attempted to collect interview data by phone from patient/parent: (1)

c. Attempted to gain patient/parent cooperation: (1)

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

_____
specify

E. Administrative information

14. Clinical Coordinator PIN: ____ ____ ____

15. Clinical Coordinator signature:

_____

16. Date form reviewed:

____ – ____ ____ ____ ____ – ____ ____
day mon year

STOP-NAFLD

Keyed: ( )

PE - Physical Examination

Purpose: Record detailed physical exam findings.

When: Visits s and f24.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Details of the protocol for height, weight, waist, hip, and blood pressure measurements are found in the STOP-NAFLD SOP, Part I. In brief: Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. If patient's weight is <70 kg (154 lbs) or >150 kg (330 lbs) at screening visit the patient is ineligible and the PE form should not be keyed. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other. Measure the hips at the fullest part. Repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other. Three blood pressure measurements should be obtained at each visit.

If patient has Stage 2 hypertension or if the average screening systolic blood pressure is >140 or the average diastolic blood pressure is >90, patient is ineligible. If the average systolic blood pressure is <90 or the average diastolic blood pressure is <60, physician should check for symptoms of hypotension.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____ - ____ ____ ____ - ____ ____
day mon year

5. Visit ID code: ____ ____ ____

6. Form & revision: **p e 2**

7. Study: : STOP-NAFLD 9

B. Measurements

8. Height *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

9. Weight *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Pounds (1)

Kilograms (2)

10. Waist *(standing, at midpoint between highest point of iliac crest and lowest part of costal margin; repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

11. Hip *(standing, at fullest part of the hips; repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

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 circumference

b. 2nd measurement:

____ ____ • ____
arm circumference

c. Units for arm circumference:

Inches (1)
Centimeters (2)

13. Temperature *(oral)*

a. Degrees: ____ ____ ____ • ____

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

15. Resting radial pulse: ____ ____ ____ beats/minute

16. Respiratory rate: ____ ____ breaths/minute

C. Examination findings

17. Skin:

Normal (1)
→ **20**

Abnormal (2)

18. Acanthosis nigricans *(check only one):*

Absent *(not detectable on close inspection)* (0)

Present *(clearly present on close inspection, not visible to casual observer, extent not measurable)* (1)

Mild *(limited to base of skull, not extending to lateral margins of neck, <3 inches in breadth)* (2)

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)
d. Striae: (1)
e. Skin lesions: (1)
f. Other *(specify):* (1)

_____

g. None of the above: (1)

20. Head, eyes, ears, nose, throat:

Normal (1)
→ **21**

Abnormal (2)

_____
specify abnormality

21. Neck:

Normal (1)
→ **22**

Abnormal (2)

_____
specify abnormality

22. Lymphatic:

Normal (1)
→ **23**

Abnormal (2)

_____
specify abnormality

23. Chest and lungs:

Normal (1)

24

Abnormal (2)

_____
specify abnormality

24. Heart:

Normal (1)

25

Abnormal (2)

_____
specify abnormality

25. Abdomen:

Normal (1)

27

Abnormal (2)

26. Abdomen abnormality *(check all that apply)*

a. Ascites: (1)

b. Obese: (1)

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

____ ____ • ____
cm

d. Splenomegaly: (1)

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

_____

27. Extremities:

Normal (1)

29

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)

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

_____

29. Nervous system:

Not performed (0)

Normal (1)

Abnormal (2)

_____
specify abnormality

D. Eligibility check

30. Is this the screening visit:

Yes (1) No (2)

34

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

Yes (1) No (2)

Elig

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:

Yes (1) No (2)

Elig

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:

Yes (1) No (2)

C

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

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

STOP-NAFLD

Keyed: ( )

PF - Focused Physical Examination

Purpose: Record focused physical exam findings.

When: Visits f04, f12, f36.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

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

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____ - ____ ____ ____ - ____ ____
day mon year

5. Visit ID code: **f** ____ ____

6. Form & revision: **p** **f** **2**

7. Study: : STOP-NAFLD 9

B. Measurements

8. Height *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

9. Weight *(shoes off)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Pounds (1)

Kilograms (2)

10. Waist *(standing, at midpoint between highest point of iliac crest and lowest part of costal margin; repeat waist measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

11. Hip *(standing, at fullest part of the hips; repeat hip measurements until you have two measurements within 4 in (10.2 cm) of each other)*

a. 1st measurement:

____ ____ ____ • ____

b. 2nd measurement:

____ ____ ____ • ____

c. Units:

Inches (1)

Centimeters (2)

12. Temperature *(oral)*

a. Degrees: ____ ____ ____ • ____

b. Scale:

Fahrenheit: (1)

Centigrade: (2)

13. 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

14. Resting radial pulse: ____ ____ ____ beats/minute

15. Respiratory rate: ____ ____ 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)

_____
specify abnormality

D. Administrative information

18. Study Physician ID: ____ ____ ____

19. Study Physician signature:

_____

20. Clinical Coordinator ID: ____ ____ ____

21. Clinical Coordinator signature:

_____

22. Date form reviewed:

____ ____ - ____ ____ ____ - ____ ____
day mon year

STOP-NAFLD

PL - Patient Location

Purpose: To record patient location and contact information.
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 identification

1. Clinic ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s ____ ____

6. Form & revision: p l 1

7. Study: STOP-NAFLD 9

B. Personal data on patient

8. Name:

_____
last name, first name, middle initial

_____
other name(s) used (if applicable)

9. Home address:

_____
number and street (apartment # if applicable)

_____
city, state, zip code

10. Telephone numbers

a. Home:

_____
(area code) telephone number

b. Cell:

_____
(area code) telephone number

c. Work:

_____
(area code) telephone number

d. Pager:

_____
(area code) telephone number

11. E-mail address:

_____
e-mail address

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:

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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQL™ 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

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date form completed:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: **p q 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: _____ _____ _____
b. Signature:

_____

10. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

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

EMOTIONAL 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

SOCIAL 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

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

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.

Keyed: ( )

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 PedsQL™ 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **p q 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

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

FUNCIONAMENTO EMOCIONAL *(problemas con...)*	**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

FUNCIONAMIENTO 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

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

FUNCIONAMIENTO 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

FUNCIONAMENTO ESCOLAR *(problemas con...)*	**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!

Keyed: ( )

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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQL™ 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

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date form completed:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: **p r 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: _____ _____ _____
b. Signature:

_____

10. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

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...

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

EMOTIONAL 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

SOCIAL 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

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

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.

Keyed: ( )

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 PedsQL™ 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

1. Center ID: _____ _____ _____ _____

2. Patient ID: _____ _____ _____ _____

3. Patient code: _____ _____ _____

4. Date form completed:

_____ _____-_____ _____ _____-_____ _____
day mon year

5. Visit code: _____ _____ _____

6. Form & revision: **p r 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: _____ _____ _____
b. Signature:

_____

10. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

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...

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

FUNCIONAMENTO EMOCIONAL *(problemas con...)*	**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: __ __ __

FUNCIONAMIENTO 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

FUNCIONAMENTO ESCOLAR *(problemas con...)*	**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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQL™ 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **p w 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day 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...

ABOUT 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

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.

Keyed: ( )

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. 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 PedsQL™ 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **p w 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __

PW - Inventario Sobre Calidad de Vida Pediátrica: Reporte de Niños (edades 8-12)

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

SOBRE MI SALUD Y ACTIVIDADES *(problemas con...)*	**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

SOBRE 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...)*	**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

SOBRE 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 re-attached to pages 2-3 and the Clinical Coordinator should complete section B. The NASH CRN has contracted with the PedsQL™ 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **p y 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___ ___

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

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

ABOUT 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

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

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 PedsQL™ 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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: **p y 1**

7. Study: STOP-NAFLD 9

B. Administrative information

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

8. How was the Pediatric Quality of Life questionnaire completed:

Self-administered in English (1)
Self-administered in Spanish (2)
Interview in English (3)
Interview in Spanish (4)

9. Clinical Coordinator
a. PIN: ____ ____ ____
b. Signature:

_____

10. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

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…

SOBRE MI SALUD Y ACTIVIDADES *(problemas con...)*	**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

SOBRE 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...)*	**Nunca**	**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

SOBRE 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!

Keyed: ( )

STOP-NAFLD

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s ____ ____

6. Form & revision: r c 1

7. Study: STOP-NAFLD 9

B. STOP-NAFLD participation

8. Date in item 4 of original STOP-NAFLD RG form:

____ ____–____ ____ ____–____ ____
day mon year

C. Administrative information

9. Clinical Coordinator PIN: ____ ____ ____

10. Clinical Coordinator signature:

_____

11. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

STOP-NAFLD 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:

____ ____ - ____ ____ ____ - ____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: r d 2

7. Study: STOP-NAFLD 9

B. Study drug dispensing

8. Will study drug be dispensed today:

Yes (* 1) No (2) → 14.

** Give dosing instruction sheet to patient.*

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

Bottle tear-off label

10.

Affix label here

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:

Yes (1) → 22. No (2)

C. Study drug return

14. Were any bottles returned at this visit:

Yes (1) No (2) → 18.

15. Number of bottles returned: ____ ____ (01-02)

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

D. Study drug compliance

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

Yes (1) No (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:

Yes (1) No (2)

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

____ ____
(00-02)

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)

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

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

____ ____
(00-02)

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:

____ ____ - ____ ____ ____ - ____ ____
day mon year

STOP-NAFLD

RG - Registration

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 INELIG is checked for any item, the patient is not eligible for STOP-NAFLD and the form should not be keyed.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: s ____ ____

6. Form & revision: r g 1

7. Study: STOP-NAFLD 9

B. Consent

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:

Yes (1) No (2) STOP

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

Yes (1) No (2) STOP

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

Yes (1)
No (2) STOP
Not using assent (3)
Not using assent for this age child (4)

C. Information about patient

11. Date of birth:

____ ____–____ ____ ____–____ ____ ____ ____
day month year

Record 4-digit year for date of birth.

12. Age at last birthday: ____ ____
years

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

Yes (1) No (2) Elig

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):*

Hispanic or Latino or Latina (1)
Not Hispanic, not Latino, not Latina (2)

17.

16. What describes the patient's Hispanic, Latino, or Latina origin best *(show the patient/guardian Flash Card #1 and ask the respondent to pick the subcategory that best describes the patient's Hispanic, Latino, or Latina origin; check only one):*

Mexican	(1)
Puerto Rican	(2)
Cuban	(3)
South or Central American	(4)
Other Spanish culture or origin	(5)

_____
specify

17. Racial category *(show the patient/guardian Flash Card #2 and ask the respondent to pick the category or categories that describe the patient best; check all that apply)*

a. American Indian or Alaska Native:	(1)
b. Asian:	(1)
c. Black, African American, Negro, or Haitian:	(1)
d. Native Hawaiian or other Pacific Islander:	(1)
e. White:	(1)
f. Patient/guardian refused:	(1)

18. In what country was the patient born *(check only one):*

Continental US (includes Alaska) or Hawaii	(1)
Other, *(specify):*	(2)

_____
specify

19. Patient's current grade level in school (or home school) *(show the patient/guardian Flash Card #3 and ask the respondent to pick the category that describes the patient best; if summer time, report grade entering in the fall; check only one):*

Grades 1 to 5	(1)
Grades 6-8	(2)
Grades 9-12	(3)
Other, *(specify):*	(4)

_____
specify

20. Combined annual income before taxes of all members of patient's household *(show guardian Flash Card #4 and ask respondent to pick the category that describes the patient's combined household income best; check only one):*

Less than $15,000	(1)
$15,000 - $29,999	(2)
$30,000 - $49,999	(3)
$50,000 or more	(4)

21. Current age of patient's mother, stepmother, or female guardian *(show patient/parent Flash Card #5; check only one):*

Not applicable (mother is deceased or patient has no stepmother or female guardian)	(0)
19 or younger	(1)
20-29 years	(2)
30-39 years	(3)
40-49 years	(4)
50-59 years	(5)
60 years or older	(6)

22. Highest educational level achieved by patient's mother, stepmother, or female guardian *(show patient/parent Flash Card #6; if education of mother or female 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	(4)

23. Current age of patient's father, stepfather, or male guardian *(show patient/parent Flash Card #5; check only one):*

Not applicable (father is deceased or patient has no stepfather or male guardian)	(0)
19 or younger	(1)
20-29 years	(2)
30-39 years	(3)
40-49 years	(4)
50-59 years	(5)
60 years or older	(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	(4)

D. Previous registration in a NASH CRN study

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

(Yes 1) (No 2)

29. ___

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

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

_____
specify

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

F. Administrative information

30. Clinical Coordinator PIN: ___ ___ ___

31. Clinical Coordinator signature:

_____

32. Date form reviewed:

___ ___ – ___ ___ ___ – ___ ___
day mon year

STOP-NAFLD

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.

When: Visit rz.

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 Elig 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 is initiated):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: r z ____

6. Form & revision: r z 1

7. Study: STOP-NAFLD 9

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:

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

10. ____

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

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

Elig

C. Alcohol use exclusions

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

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

Elig

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

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

Elig ____

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:

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

Elig ____

D. Laboratory test exclusions

13. Hepatic Decompensation

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

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

14. Other laboratory measures

a. Is serum ALT greater than 300 IU/L:

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

c. Is the patient's platelet count less than 100,000 cells/mm^3:

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

E. Medication use exclusions

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

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

17. Current daily use of NSAIDS:

( ) Yes 1 → Elig ( ) No 2

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:

( ) Yes 1 → Elig ( ) No 2

F. Other chronic liver disease exclusions

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

( ) Yes 1 → Elig ( ) No 2

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:

( ) Yes 1 → Elig ( ) No 2

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

( ) Yes 1 → Elig ( ) No 2

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):

Yes (1) → Elig No (2)

23. Do any of the patient's assessments show evidence of other chronic liver disease

a. Suspected or proven liver cancer:

Yes (1) → Elig No (2)

b. Hepatitis B (HBsAg):

Yes (1) → Elig No (2)

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

Yes (1) → Elig No (2)

d. Any other type of liver disease other than NASH that warrants exclusion from the trial:

Yes (1) → Elig No (2)

G. Liver biopsy exclusions

24. Presence of cirrhosis on liver biopsy:

Yes (1) → Elig No (2)

25. Inability to safely undergo a liver biopsy:

Yes (1) → Elig No (2)

26. Biopsy out of window and patient chose not to repeat:

Yes (1) → Elig No (2)

27. Biopsy inadequate for scoring and patient chose not to repeat:

Yes (1) → Elig No (2)

28. Local pathologist did not find NAFLD:

Yes (1) → Elig No (2)

29. NAFLD activity score (NAS) less than 3:

Yes (1) → Elig No (2)

H. Other medical exclusions

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

Yes (1) → Elig No (2)

31. History of biliary diversion:

Yes (1) → Elig No (2)

32. Known positivity for HIV infection:

Yes (1) → Elig No (2)

33. History of hypotension or history of orthostatic hypotension:

Yes (1) → Elig No (2)

34. Stage 2 hypertension or greater than 140 systolic or greater than 90 diastolic at screening:

Yes (1) → Elig No (2)

35. History of kidney disease and/or eGFR less than 60 mL/min/1.73 m^2:

Yes (1) → Elig No (2)

36. Known active substance abuse (inhaled or injected) in the past 12 months:

Yes (1) → Elig No (2)

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

( ) Yes (1) → Elig
( ) No (2)

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

( ) Yes (1) → Elig
( ) No (2)

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

( ) Yes (1) → Elig
( ) No (2)

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

( ) Yes (1) → Elig
( ) No (2)

I. Weight exclusion

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

( ) Yes (1) → Elig
( ) No (2)

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):*

( ) Yes (1)
( ) No (2) → Elig

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):*

( ) Yes (1)
( ) No (2) → Elig

L. Eligibility check on day of randomization

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

( ) Yes (1) → **54.**
( ) No (*2)

**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:

Yes ( ) (1) → **54.**
No ( ) (2)
Task not run because patient is known to be ineligible ( ) (3) → **54.**

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

( ) Yes (1)
( ) No (*2) → Elig

**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:

( ) Yes (1) → **51.**
( ) No (2)

48. Is the patient of childbearing potential:

( ) Yes (*1)
( ) No (2) → **51.**

**Administer pregnancy test.*

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

( ) Yes (*1) → Elig
( ) No (2)

**Go to item 54.*

50. Is the patient currently breast feeding

Yes (*1) No (2)

Go to item 54.

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

Yes (*1) No (2)

**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:

Yes (1) No (*2)

**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):*

Yes (*1) No (†2)

55.

**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: (1)

b. Other reason not covered on this form *(specify):* (1)

_____
specify

N. Administrative information

55. Study Physician PIN: ___ ___ ___

56. Study Physician signature:

_____

57. Clinical Coordinator PIN: ___ ___ ___

58. Clinical Coordinator signature:

_____

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.):

___ ___–___ ___ ___–___ ___
day mon year

STOP-NAFLD

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 identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form initiated:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____

6. Form & revision: s d 1

7. Study: STOP-NAFLD 9

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:

Yes (1) No (*2) → STOP

** 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

b. Lobe specimen obtained from *(check only one):*

Right (1)
Left (2)
Unknown (3)

C. Requirements for screening biopsy

10. Is this visit s:

Yes (1) No (2) → **12.**

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

Yes (1) No (*2) → C

** 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 stain: (1)

b. Masson's trichrome stain: (1)

c. Iron stain: (1)

E. Unstained slides to be sent to the DCC

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

Yes (* 1) No (2)

25. ____

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

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

Yes (1) No (2)

17. ____

15. How many unstained slides will be sent to the DCC: ____ ____ (01-10)

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):*

a. Slide sequence number ____ ____ (01-60)

b. Slide sequence number ____ ____ (01-60)

c. Slide sequence number ____ ____ (01-60)

d. Slide sequence number ____ ____ (01-60)

e. Slide sequence number ____ ____ (01-60)

f. Slide sequence number ____ ____ (01-60)

g. Slide sequence number ____ ____ (01-60)

h. Slide sequence number ____ ____ (01-60)

i. Slide sequence number ____ ____ (01-60)

j. Slide sequence number ____ ____ (01-60)

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:

Yes (1) No (2)

25. ____

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: ____ ____ (81-90)

b. Slide sequence number of Masson's trichrome stain: ____ ____ (81-90)

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

d. Slide sequence number of other stain: ____ ____ (81-90)

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

Yes (1) No (2)

25. ____

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: ____ ____ (81-90)

c. Slide sequence number: ____ ____ (81-90)

d. Slide sequence number: ____ ____ (81-90)

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

Immediately after central review (1)

At the end of the NASH CRN funding period (2)

24. Which pathology department did these slides come from:

NASH CRN clinical center's pathology department (1)

25. ___

Other, *(specify):* (2)

_____
name

_____
address

_____
address

_____
address

_____
phone

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

Keyed: ( )

STOP-NAFLD

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of report: ____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: ____ ____ ____
If report not associated with a visit, fill in "n."

6. Form & revision: s r 1

7. Study: STOP-NAFLD 9

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: ____ ____
years

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)
15.
Definitely no (5)
15.

12. Is this a serious adverse event:

Yes (1) No (2)
15.

If Yes, then select all the reasons that apply:

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)
e. Congenital anomaly or birth defect: (1)

13. Is this an unexpected adverse event:

Yes (1) No (2)
15.

14. Reason the adverse event was unexpected:

Not listed in the losartan potassium investigator brochure (1)
Listed in the losartan potassium investigator's brochure, but not at the specificity or severity that has been observed (2)
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 experience of losartan potassium (3)

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

Yes (*1) No (†2)
STOP

**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 (1)
Followup report (2)

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:

_____
_____
_____
_____
_____

21. Specify tests/treatments and comorbidities:

_____
_____
_____
_____
_____

22. Was an unscheduled liver biopsy performed:

Yes (* 1) No (2)

**Attach a copy of the institutional pathology report to the SR form.*

23. Did the serious adverse event result in significant sequelae:

Yes (1) No (2)

24.

Specify:

_____
_____
_____
_____

24. Short name for serious adverse event *(short names for AEs are listed in the CTCAE v5.0 document available at www.nashcrn.com; click on Studies and then click on STOP-NAFLD):*

_____
_____

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):*

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

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

26. Current status of serious adverse event *(check only one):*

Resolved (1)
Active (2)
28.
Unknown (3)
28.

27. Date resolved:

____ ____–____ ____ ____–____ ____
day mon year

28. Additional comments on serious adverse event:

_____
_____
_____
_____

E. Administrative information

29. Study Physician PIN: ____ ____ ____

30. Study Physician signature:

_____

31. Clinical Coordinator PIN: ____ ____ ____

32. Clinical Coordinator signature:

_____

33. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

Key this form and send the DCC within 1 business day:

(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.

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. Mariana Lazo, the Safety Officer, and NIDDK (Sponsor).

Keyed: ( )

STOP-NAFLD

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

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of notification of intent to transfer:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: n ____ ____

6. Form & revision: t n 1

7. Study: STOP-NAFLD 9

B. Last follow-up visit information

8. Date of last follow-up visit:

____ ____–____ ____ ____–____ ____
day mon year

9. Visit ID code of last completed follow-up visit: f ____ ____

10. Have cryovial and slide labels been sent to the adopting center:

(Yes 1) (No * 2)

** Send the cryovial and slide labels to the adopting center (using a package tracking service).*

C. Enrolling center administrative information

11. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

12. Clinical coordinator ID: ____ ____ ____

13. Clinical coordinator signature:

_____

D. Adopting center, patient and visit identification

14. Adopting center ID: ____ ____ ____ ____

15. Patient ID *(must be same as in Section A):*

____ ____ ____ ____

16. Patient code: *(must be same as in Section A):*

____ ____ ____

17. Expected date of first follow-up visit at adopting center:

____ ____–____ ____ ____–____ ____
day mon year

18. Visit ID code for expected first follow-up visit at adopting center: f ____ ____

Reminder: Please follow your local IRB requirements regarding consent and HIPAA statements.

E. Adopting center administrative information

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

20. Clinical coordinator ID: ____ ____ ____

21. Clinical coordinator signature:

_____

Fax form to the DCC. The DCC will key the TN form.