Gastroparesis Registry

BH - Baseline Medical History

Purpose: To collect baseline history information about the patient.
When: Screening visit b.
Administered by: Clinical Coordinator, reviewed by Study Physician.
Respondent: Patient.
Instructions: Collect information by interview and/or chart review. If (c) is checked for an item, further review is necessary. If the physician agrees with the diagnosis, the patient is ineligible for the Gastroparesis Registry. If (Elig) is checked for an item, the patient is ineligible and cannot enroll in the Gastroparesis Registry. 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: b ___ ___ ___

6. Form & revision: b h 2

7. Study: Gastroparesis Registry 1

B. Gastroparesis history

8. Date symptoms of gastroparesis or functional dyspepsia started: ___ ___ – ___ ___ – ___ ___ (day, mon, year)

9. What is the present understanding of the reason for patient's gastroparesis *(check all that apply)*

- **a.** Diabetes: (1)
- **b.** Post-surgical: (1)
- **c.** Idiopathic: (1)
- **d.** Ischemic *(chronic mesenteric ischemia):* (1)
- **e.** Other *(specify):* (1)

__________________ specify

10. Did the patient have an initial infectious prodrome with resultant chronic GI motility symptoms:

Yes (1) No (2) → **12.**

11. Specify infectious symptoms *(check best response)*

- **a.** Upper respiratory flu-like illness *(fever, cough, body aches):* (1)
- **b.** Food-poisoning like symptoms *(nausea, vomiting after eating bad food):* (1)
- **c.** Gastroenteritis *(nausea, vomiting, diarrhea):* (1)
- **d.** Other *(specify):* (1)

__________________ specify

12. What prompted the evaluation for gastroparesis: *(check all that apply)*

- **a.** Nausea: (1)
- **b.** Vomiting: (1)
- **c.** Bloating: (1)
- **d.** Early satiety *(a sense that your stomach is full after eating only a small amount of food):* (1)
- **e.** Postprandial fullness *(a sense of fullness after the meal):* (1)
- **f.** Abdominal pain: (1)
- **g.** Diarrhea: (1)
- **h.** Constipation: (1)
- **i.** Anorexia: (1)
- **j.** Weight loss: (1)
- **k.** Weight gain: (1)
- **l.** Gastroesophageal reflux symptoms such as heartburn: (1)
- **m.** Problems with the management of diabetes or glycemic control: (1)
- **n.** Other *(specify):* (1)

____
specify

13. Select the predominant symptom listed in item 12 (a through n): ____

14. Which best describes the onset of gastroparesis symptoms *(check only one):*

- Acute start (1)
- Insidious (2)
- Other *(specify):* (3)

____
specify

15. Which best describes the nature of gastroparesis symptoms *(check only one):*

- Chronic, but stable symptoms (1)
- Chronic, but progressive worsening of symptoms (2)
- Chronic symptoms with periodic exacerbations (3)
- Cyclic pattern of exacerbations with periods of feeling well in between (4)
- Other *(specify):* (5)

____
specify

16. Which best describes the gastroparesis severity *(check only one):*

- (Grade 1) Mild gastroparesis: *Symptoms relatively easily controlled. Able to maintain weight and nutrition on a regular diet.* (1)
- (Grade 2) Compensated gastroparesis: *Moderate symptoms with only partial control with use of daily medications. Able to maintain nutrition with dietary adjustments.* (2)
- (Grade 3) Gastroparesis with gastric failure: *Refractory symptoms that are not controlled. Having ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via oral route.* (3)
- Other *(specify):* (4)

____
specify

17. Has the patient ever had a formal nutrition consult at any time after the onset of gastroparesis:

Yes (1) No (2)

C. Tobacco cigarette smoking history *(interview with patient; not by chart review)*

18. Have you ever smoked tobacco cigarettes:

- Never (1) → **23.**
- In the past but not anymore (2)
- Currently smokes cigarettes (3)

19. 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) → **23.**

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

___ ___ years

21. How old were you when you (last) stopped smoking cigarettes *(code as "n" if the patient did not stop smoking):*

___ ___ years

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

___ ___ ___ cigarettes/day

D. Alcohol consumption (AUDIT-C) history *(interview with patient; not from chart review)*

23. How often have you had a drink containing alcohol in the past year *(check only one):*

Never	(0) → **26.**
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)

24. How many drinks containing alcohol have you had on a typical day when you are drinking *(check only one):*

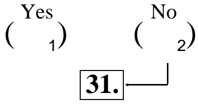
1 or 2	(0)
3 or 4	(1)
5 or 6	(2)
7 to 9	(3)
10 or more	(4)

25. How often have you had six or more drinks on one occasion *(check only one):*

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

E. Menstrual history

26. Is the patient female:



Yes (1) No (2) → **31.**

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

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

28. Is patient postmenopausal:

Yes (1) No (2) → **30.**

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

___ ___ age in years

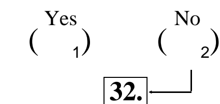
30. Did the patient have a hysterectomy:

Yes (1) No (2)

F. Medical history

(⚠c means Caution; condition is exclusionary if study physician agrees with diagnosis)

31. Has the patient ever been diagnosed with diabetes:



Yes (1) No (2) → **32.**

a. Diabetes type:

Type 1:	(1)
Type 2:	(2)
Unknown:	(3)

b. Age when diagnosed:

___ ___ age in years

32. 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. Gestational diabetes *(diabetes of pregnancy):* (1)

b. Pyloric obstruction: (1) C

c. Intestinal obstruction: (1) C

d. Inflammatory bowel disease: (1) C

e. Eosinophilic gastroenteritis: (1) C

f. Acute renal failure: (1) C

g. Acute liver failure: (1) C

h. Advanced liver disease *(Child's B or C; a CPT score of 7 or greater):* (1) C

i. Hepatitis B: (1)

j. Hepatitis C: (1)

k. Peptic ulcer disease: (1)

l. GERD: Gastroesophageal reflux disease: (1)

m. Interstitial cystitis: (1)

n. Bladder dysfunction: (1)

o. Diverticulosis: (1)

p. Endometriosis: (1)

q. Blood clots: (1)

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

s. Systemic autoimmune disorder such as rheumatoid arthritis: (1)

t. Scleroderma: (1)

u. Thyroid disease *(hormonal abnormality):* (1)

v. Malignancy *(cancer):* (1)

w. Peripheral neuropathy: (1)

x. Migraine headaches: (1)

y. Seizure disorder or epilepsy: (1)

z. Chronic fatigue syndrome: (1)

aa. Hypertension: (1)

ab. Coronary artery disease: (1)

ac. Cerebrovascular disease: (1)

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

ae. Pancreatitis: (1)

af. Cholelithiasis: (1)

ag. Gallbladder disease including chronic cholecystitis, gallbladder dyskinesia: (1)

ah. Gout: (1)

ai. Polycystic ovary syndrome: (1)

aj. Dermatologic disorders: (1)

ak. Myopathy: (1)

al. Fibromyalgia: (1)

am. Multiple sclerosis: (1)

an. Parkinson's disease: (1)

ao. ALS: Amyotrophic lateral sclerosis: (1)

ap. Eating disorders *(anorexia, bulimia):* (1)

aq. Major depression: (1)

ar. Schizophrenia: (1)

as. Bipolar disorder: (1)

at. Obsessive compulsive disorder: (1)

au. Severe anxiety or personality disorder: (1)

av. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)

aw. Systemic lupus erythematosus: (1)

ax. Collagen vascular disease: (1)

ay. Other unidentified systemic autoimmune disorder: (1)

az. None of the above: (1)

33. Has the patient ever had any abdominal procedures:

Yes ($_1$) No ($_2$) → **34.**

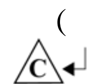
(Please check all that apply):

a. Total gastric resection: ($_1$)

b. Subtotal gastric resection *(vagotomy, pyloroplasty, antrectomy):* ($_1$)

c. Stapling or banding of the stomach: ($_1$)

d. Fundoplication for GERD: ($_1$)



e. Gastrojejunostomy: ($_1$)

f. Cholecystectomy: ($_1$)

g. Endoscopy: ($_1$)

h. Other GI procedure *(specify):* ($_1$)

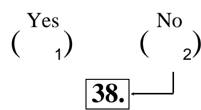
____
specify

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

Yes ($_1$) No ($_2$)

35. Was the patient hospitalized for gastroparesis in the past year:

Yes ($_1$) No ($_2$)



36. How many times has the patient been hospitalized for gastroparesis in the past year: ___ ___

37. Reason(s) for hospitalization *(check all that apply):*

a. Intractable nausea and vomiting: ($_1$)

b. Abdominal pain: ($_1$)

c. Dehydration: ($_1$)

d. Hyperglycemia: ($_1$)

e. GI bleed: ($_1$)

f. Other *(specify):* ($_1$)

____
specify

G. Nutrition and Gastric Electrical Stimulator (GES) Use

38. Does the patient have a G tube:

Yes ($_1$) No ($_2$) → **40.**

a. G tube has been in place since:

___ ___ – ___ ___ ___ ___
month year

39. What does the patient use this G tube for *(check all that apply):*

a. Nutrition: ($_1$)

b. Hydration: ($_1$)

c. Medication: ($_1$)

d. Decompression: ($_1$)

e. Other *(specify):* ($_1$)

____
specify

40. Does the patient have a J tube:

Yes (1) No (2) → **42.**

a. J tube has been in place since:

___ ___ ___–___ ___
month year

41. What does the patient use this J tube for *(check all that apply):*

a. Nutrition: (1)

b. Hydration: (1)

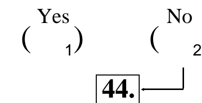
c. Medication: (1)

d. Decompression: (1)

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

____
specify

42. Does the patient have a central line/PICC:



a. Central line/PICC has been in place since:

___ ___ ___–___ ___
month year

43. What does the patient use this central line/PICC for *(check all that apply):*

a. Nutrition: (1)

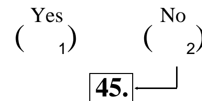
b. Hydration: (1)

c. Medication: (1)

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

____
specify

44. Does the patient have a gastric electrical stimulator (GES):



a. Gastric electrical stimulator (GES) has been in place since:

___ ___ ___–___ ___
month year

b. Is gastric electrical stimulator (GES) currently turned on:

Yes (1) No (2)

45. What is the patient's source of nutrition *(check all that apply):*

a. Oral feeding: (1)

b. Enteral feeding: (1)

c. Parenteral feeding: (1)

H. Medication use

46. Is the patient currently taking any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications:

Yes (1) No (2) → **47.**

(If yes or unsure, check all that apply):

a. Esomeprazole (Nexium): (1)

b. Omeprazole (Prilosec, Zegerid): (1)

c. Lansoprazole (Prevacid): (1)

d. Pantoprazole (Protonix): (1)

e. Rabeprazole (Aciphex): (1)

f. Ranitidine (Zantac): (1)

g. Famotidine (Pepcid): (1)

h. Nizatidine (Axid): (1)

i. Cimetidine (Tagamet): (1)

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

____
specify

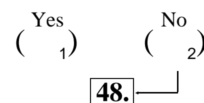
k. Other *(specify):* (1)

____
specify

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

____
specify

47. Is the patient currently taking any prokinetic medications for gastroparesis:



(If yes or unsure, check all that apply):

a. Azithromycin (Zithromax): (1)

b. Bethanechol (Duvoid, Urecholine): (1)

c. Botulinum toxin (Botox) within the last 4 weeks: (1)

d. Cisapride (Propulsid): (1)

e. Clarithromycin (Biaxin): (1)

f. Domperidone (Motilium): (1)

g. Erythromycin: (1)

h. Metoclopramide (Reglan): (1)

i. Tegaserod (Zelnorm): (1)

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

____
specify

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

____
specify

48. Has the patient used and discontinued any prokinetic medications for gastroparesis in the past 6 months:

Yes (1) No (2) → **49.**

(If yes or unsure, check all that apply):

a. Azithromycin (Zithromax): (1)

b. Bethanechol (Duvoid, Urecholine): (1)

c. Botulinum toxin (Botox): (1)

d. Cisapride (Propulsid): (1)

e. Clarithromycin (Biaxin): (1)

f. Domperidone (Motilium): (1)

g. Erythromycin: (1)

h. Metoclopramide (Reglan): (1)

i. Tegaserod (Zelnorm): (1)

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

____
specify

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

____
specify

49. Is the patient currently using any of the following medications:

Yes (1) No (2) → **50.**

(If yes or unsure, check all that apply):

a. Prochlorperazine (Compazine): (1)
b. Promethazine (Pentazine, Phenergan): (1)
c. Trimethobenzamide (Benzacot, Stemetic, Tigan): (1)
d. Meclizine (Antivert): (1)
e. Ondansetron (Zofran): (1)
f. Tropisetron (Navoban): (1)
g. Granisetron (Kytril): (1)
h. Palonosetron (Aloxi): (1)
i. Dolasetron (Anzemet): (1)
j. Lorazepam (Ativan): (1)
k. Aprepitant (Emend): (1)
l. Amitriptyline (Elavil): (1)
m. Desipramine (Norpramin): (1)
n. Nortriptyline (Aventyl, Pamelor): (1)
o. Tetrahydrocannabinol: (1)
p. Dronabinol (Marinol): (1)
q. Mirtazapine (Remeron): (1)
r. Bupropion (Wellbutrin): (1)
s. Citalopram (Celexa): (1)
t. Escitalopram (Lexapro): (1)
u. Fluoxetine (Prozac): (1)
v. Paroxetine (Paxil): (1)
w. Sertraline (Zoloft): (1)
x. Venlafaxine (Effexor): (1)
y. Alprazolam (Xanax): (1)
z. Buspirone (BuSpar): (1)
aa. Chlordiazepoxide (Librax): (1)
ab. Diazepam (Valium): (1)
ac. Oxazepam (Serax): (1)
ad. Clonazepam (Klonopin): (1)
ae. Halazepam (Paxipam): (1)
af. Meprobamate (Equanil, Meprospan): (1)
ag. Quetiapine fumarate (Seroquel): (1)
ah. Other *(specify):* (1)

____
specify

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

____
specify

50. Has the patient used and discontinued any of the following medications for gastroparesis in the past 6 months:

Yes (1) No (2) → **51.**

(If yes or unsure, check all that apply):

a. Prochlorperazine (Compazine): (1)
b. Promethazine (Pentazine, Phenergan): (1)
c. Trimethobenzamide (Benzacot, Stemetic, Tigan): (1)
d. Meclizine (Antivert): (1)
e. Ondansetron (Zofran): (1)
f. Tropisetron (Navoban): (1)
g. Granisetron (Kytril): (1)
h. Palonosetron (Aloxi): (1)
i. Dolasetron (Anzemet): (1)
j. Lorazepam (Ativan): (1)
k. Aprepitant (Emend): (1)
l. Amitriptyline (Elavil): (1)
m. Desipramine (Norpramin): (1)
n. Nortriptyline (Aventyl, Pamelor): (1)
o. Tetrahydrocannabinol (THC, marijuana): (1)
p. Dronabinol (Marinol): (1)
q. Mirtazapine (Remeron): (1)
r. Bupropion (Wellbutrin): (1)

s. Citalopram (Celexa): (1)

t. Escitalopram (Lexapro): (1)

u. Fluoxetine (Prozac): (1)

v. Paroxetine (Paxil): (1)

w. Sertraline (Zoloft): (1)

x. Venlafaxine (Effexor): (1)

y. Alprazolam (Xanax): (1)

z. Buspirone (BuSpar): (1)

aa. Chlordiazepoxide (Librax): (1)

ab. Diazepam (Valium): (1)

ac. Oxazepam (Serax): (1)

ad. Clonazepam (Klonopin): (1)

ae. Halazepam (Paxipam): (1)

af. Meprobamate (Equanil, Meprospan): (1)

ag. Quetiapine fumarate (Seroquel): (1)

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

____
specify

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

____
specify

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

Yes (1) No (2) → **52.**

(If yes or unsure, check all that apply):

a. Insulin: (1)

b. Acarbose (Precose): (1)

c. Acetohexamide (Dymelor): (1)

d. Chlorpropamide (Diabinese): (1)

e. Glimepiride (Amaryl): (1)

f. Glipizide (Glucotrol): (1)

g. Glyburide (Micronase, DiaBeta, Glynase): (1)

h. Metformin (Glucophage): (1)

i. Miglitol (Glycet): (1)

j. Nateglinide (Starlix): (1)

k. Pioglitazone (Actos): (1)

l. Repaglinide (Prandin): (1)

m. Rosiglitazone (Avandia): (1)

n. Tolazamide (Tolinase): (1)

o. Tolbutamide (Orinase): (1)

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

____
specify

52. Has the patient taken any alcohol abuse (dependance or withdrawal) medications in the past 6 months:

Yes (1) No (2) → **53.**

(If yes or unsure, check all that apply):

a. Chlordiazepoxide (Librium): (1)

b. Clorazepate dipotassium (Tranxene): (1)

c. Diazepam (Valium): (1)

d. Disulfiram (Antabuse): (1)

e. Hydroxyzine pamoate (Vistaril): (1)

f. Naltrexone hydrochloride (Revia): (1)

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

____
specify

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

Yes (1) No (2) → **54.**

(If yes or unsure, check all that apply):

a. Acetaminophen (Tylenol): (1)

b. Aspirin - 325 mg: (1)

c. Celecoxib (Celebrex): (1)

d. Ibuprofen (Advil, Motrin): (1)

e. Indomethacin (Indocin): (1)

f. Naproxen (Aleve, Naprosyn): (1)

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

______________________ specify

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

______________________ specify

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

______________________ specify

54. Is the patient currently taking any narcotic pain medications:

Yes (1) No (2) → **56.**

(If yes, check all that apply):

a. Darvocet: (1)

b. Fentanyl transdermal (Duragesic patch): (1)

c. Esgic - Plus: (1)

d. Fentanyl oral (Fentora, Actiq): (1)

e. Fioricet: (1)

f. Lorcet: (1)

g. Lortab: (1)

h. Methadone: (1)

i. Norco: (1)

j. Oxycodone: (1)

k. Oxycontin: (1)

l. Percocet: (1)

m. Percodan: (1)

n. Talacen: (1)

o. Tylenol #3: (1)

p. Tylenol #4: (1)

q. Tylox: (1)

r. Ultram (Tramadol HCl): (1)

s. Ultracet: (1)

t. Vicodin: (1)

u. Wygesic: (1)

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

______________________ specify

55. Is the patient taking the narcotic pain medication for *(check all that apply)*

a. Abdominal pain: (1)

b. Headache pain: (1)

c. Leg pain: (1)

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

______________________ specify

56. Has the patient taken any of the following neuropathic pain medications in the past 6 months:

Yes (₁) No (₂) → **57.**

(If yes or unsure, check all that apply):

a. Duloxetine (Cymbalta): (1)

b. Gabapentin (Neurontin): (1)

c. Pregabalin (Lyrica): (1)

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

____
specify

57. Has the patient taken any antihyperlipidemic medications in the past 6 months:

Yes (1) No (2) → **58.**

(If yes or unsure, check all that apply):

a. Atorvastatin (Lipitor): (1)

b. Colestipol hydrochloride (Colestid): (1)

c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (1)

d. Gemfibrozil (Gen-Fibro, Lopid): (1)

e. Fenofibrate (Tricor): (1)

f. Fluvastatin sodium (Lescol): (1)

g. Lovastatin (Mevacor): (1)

h. Nicotinic acid (Niaspan): (1)

i. Pravastatin sodium (Pravachol): (1)

j. Rosuvastatin (Crestor): (1)

k. Simvastatin (Zocor): (1)

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

____
specify

58. Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months:

Yes (1) No (2) → **59.**

(If yes or unsure, check all that apply):

a. Clopidogrel (Plavix): (1)

b. Dipyridamole (Persantine, Aggrenox): (1)

c. Heparin: (1)

d. Ticlopide (Ticlid): (1)

e. Warfarin (Coumadin): (1)

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

____
specify

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

____
specify

59. Has the patient taken any systemic corticosteroids in the past 6 months:

Yes (1) No (2) → **60.**

(If yes or unsure, 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)

____
specify

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

____
specify

60. Has the patient taken any cardiovascular/antihypertensive medications in the past 6 months:

Yes (1) No (2) → **61.**

(If yes or unsure, check all that apply):

a. Amiodarone (Pacerone): (1)

b. Amlodipine besylate (Norvasc): (1)

c. Atenolol (Tenormin): (1)

d. Benazepril (Lotensin): (1)

e. Captopril (Capoten): (1)

f. Clonidine (Catapres): (1)

g. Digoxin (Lanoxin): (1)

h. Diltiazem (Cardizem): (1)

i. Doxazosin (Cardura): (1)

j. Enalapril (Vasotec): (1)

k. Felodipine (Plendil): (1)

l. Furosemide (Lasix): (1)

m. Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)

n. Hydrochlorothiazide + triamterene (Dyazide): (1)

o. Lisinopril (Prinivil, Zestril): (1)

p. Losartan potassium (Cozaar): (1)

q. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)

r. Metoprolol (Lopressor): (1)

s. Nifedipine (Adalat, Procardia): (1)

t. Perhexiline maleate: (1)

u. Propranolol (Inderal): (1)

v. Quinapril (Accupril): (1)

w. Terazosin (Hytrin): (1)

x. Timolol maleate (Blocadren): (1)

y. Valsartan (Diovan): (1)

z. Verapamil (Calan): (1)

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

____
specify

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

____
specify

61. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months:

Yes (1) No (2) → **62.**

(If yes or unsure, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

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

g. Levonorgestrel (Norplant): (1)

h. Medroxyprogesterone (Cycrin, Provera): (1)

i. Megestrol (Megace): (1)

j. Methyltestosterone (Android): (1)

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

l. Norethindrone (Micronor): (1)

m. Norgestrel (Ovrette): (1)

n. Oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (1)

o. Oxandrolone (Oxandrin): (1)

p. Oxymetholone (Anadrol): (1)

q. Progesterone (Prometrium): (1)

r. Raloxifene (Evista): (1)

s. Tamoxifen (Nolvadex): (1)

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

____
specify

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

____
specify

62. Has the patient taken any allergy or asthma medications in the past 6 months:

Yes (1) No (2) → **63.**

(If yes or unsure, 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)

____
specify

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

____
specify

I. Alternative therapies

63. Has the patient ever used alternative medicine or complementary medicine products or procedures for treatment of their symptoms related to gastroparesis *(e.g., bloating, nausea, vomiting, abdominal pain):*

Yes (1) No (2) → **64.**

a. Acupuncture:
- Never (1)
- In the past (2)
- Currently (3)

b. Acupressure bands/bracelets:
- Never (1)
- In the past (2)
- Currently (3)

c. Reflexology:
- Never (1)
- In the past (2)
- Currently (3)

d. Hypnotherapy:
- Never (1)
- In the past (2)
- Currently (3)

e. Therapeutic Massage:
- Never (1)
- In the past (2)
- Currently (3)

f. Herbal supplements:
- Never (1)
- In the past (2)
- Currently (3)

g. Probiotics:
- Never (1)
- In the past (2)
- Currently (3)

h. Other *(specify):*
- Never (1)
- In the past (2)
- Currently (3)

____
specify

J. Administrative information

64. Study Physician PIN: ____ ____ ____

65. Study Physician signature:

____

66. Clinical Coordinator PIN: ____ ____ ____

67. Clinical Coordinator signature:

____

68. Date form reviewed:

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

Keyed: ( )

Gastroparesis Registry

DR - Death Report

Purpose: To record the report of a patient's death.
When: As soon as the 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. Fax a copy of the Death Report (DR) form to the DCC at (410) 955-0543 (attention: Wana Kim or Mika Green). Also, complete an Interim Event (IE) form and follow the instructions to report a patient's death in the Gastroparesis Registry. Please obtain a death certificate, when possible.

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 2

7. Study: Gastroparesis Registry 1

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. Health care provider or GpCRC staff: (1)
d. Newspaper: (1)
e. Funeral parlor/home: (1)
f. Medical record: (1)
g. Medical examiner: (1)
h. Coroner: (1)
i. Other *(specify)*: (1)

____
other source

____
other source

10. Place and location of death

a. Place of death *(check only one)*:

Hospital (1)
Other health care facility (2)

____
specify

Home (3)
Other *(specify)*: (4)

____
specify

b. Location of death:

____
city/state

11. Has a death certificate been obtained:

Yes (1) No (2)

12. Cause of death
(Study Physician: use all the information you have and your medical judgment to best characterize the cause of death; check only one):

Heart disease (01)
Stroke (02)
Malignancy (03)
Gastrointestinal disease (04)
Infection (05)
Suicide (06)
Accident (07)
Homicide (08)
Pulmonary disease (09)
Kidney disease (10)
Liver disease (11)
Complications of diabetes (12)
Other *(specify)*: (13)

____
specify

____
specify

13. Co-morbid disorder
(check all that apply):

- **a.** Diabetes: ($_1$)
- **b.** Heart disease: ($_1$)
- **c.** Lung disease: ($_1$)
- **d.** Malignancy: ($_1$)
- **e.** Other *(specify):* ($_1$)

specify

specify

- **f.** None of the above: ($_1$)

14. At time of death, did the patient have
(check all that apply):

- **a.** Central/PICC line: ($_1$)
- **b.** Gastric/jejunostomy tube: ($_1$)
- **c.** Electrical gastric stimulator: ($_1$)
- **d.** Other *(specify):* ($_1$)

other source

other source

- **e.** None of the above: ($_1$)

15. Include a narrative from the Study Physician as to the events surrounding the death, comorbidities, and possible cause(s) of death. Use and attach another page, if needed:

C. Administrative information

16. Study Physician PIN: ___ ___ ___

17. Study Physician signature:

18. Clinical Coordinator PIN: ___ ___ ___

19. Clinical Coordinator signature:

20. Date form reviewed:

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

Key this form and send the DCC (Attn: Wana Kim or Mika Green) the following: (1) A copy of this form; (2) A narrative description of the comorbidities or events surrounding the death, including the study physician's evaluation of the cause(s) of death; (3) A copy of the death certificate, when available. If sending a copy of the death certificate, please black-out the patient's name and any identifiable patient information.

Gastroparesis Registry

EG - Upper Endoscopy Documentation

Purpose: To document the results of any upper gastrointestinal endoscopy to determine patient eligibility during screening and to document other findings, if any, during follow-up.

When: **Screening visit b:** The screening upper gastrointestinal endoscopy procedure must have been performed within 12 months prior to registration. **Follow-up visits:** The form should be completed at each follow-up visit. If patient has had an endoscopic procedure since the last study visit, results should be recorded on this form. If no results are available, complete items 1-8 and Section G. If more than one endoscopy has been performed in the same visit window, use visit code "n" for the 2nd endoscopy, "n1" for the 3rd endoscopy, etc.

Administered by: Study Physician and Clinical Coordinator.

Baseline visit instructions: This form should be completed using the available reports (surgical and histology) of the upper gastrointestinal endoscopy procedure. Attach a copy of the available reports. If (Elig) or (STOP) is checked for any item, then STOP filling out form and do not data enter the form. If (c) is checked for any item, further review is necessary to determine eligibility status.

Follow-up visit instructions: This form should be completed using the available reports (surgical and histology) of the upper gastrointestinal endoscopy procedure. Attach a copy of the available reports. Ineligibility and Caution warnings apply to study exclusion criteria for screening, but are not applicable to follow-up visits. Disregard any (Elig) or (c) items when completing this form at follow-up.

A. Center, patient, and visit identification

1. Center ID: ___ ___ ___ ___

2. Patient ID: ___ ___ ___ ___

3. Patient code: ___ ___ ___

4. Date form is initiated: ___ ___ - ___ ___ - ___ ___ (day mon year)

5. Visit code: ___ ___ ___ ___

6. Form & revision: e g 2

7. Study: Gastroparesis Registry 1

B. Upper endoscopy information

8. Are upper endoscopy results available at this visit: Yes (1) No (2) → **23.**

a. Date of upper endoscopy: ___ ___ - ___ ___ - ___ ___ (day mon year)

b. Is this screening visit b: Yes (1) No (2) → **9.**

c. Is date within 12 months prior to the registration date: Yes (1) No (2) → STOP

(If STOP, then do not key form. The upper endoscopy must be scheduled).

9. Reason(s) for the procedure *(check all that apply):*

a. Gastroparesis symptoms/rule out obstruction: (1)

b. Anemia: (1)

c. Abdominal pain: (1)

d. Gastrostomy tube: (1)

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

________________ other specify

C. Endoscopic findings

10. Normal esophagus: Yes (1) → **11.** No (2)

(If no, check all that apply):

a. Esophagitis: (1)

b. Barrett's Esophagus: (1)

c. Hiatal hernia: (1)

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

________________ other specify

11. Normal stomach: Yes (1) → **13.** No (2)

(If no, check all that apply):

a. Gastritis: (1)

b. Ulcer: (1)

c. Polyp(s): (1) → C

d. Mass: (1) → C

e. Retained food: (1)

f. Retained bile: (1)

g. Gastrostomy tube: (1)

h. Pyloric stenosis: (1) → C

i. Other gastric findings, excluding any gastric surgery *(specify):* (1)

____
other specify

12. Surgical change(s) found in stomach: Yes (1) No (2) → **13.**

(If yes, check all that apply):

a. Total resection: (1) → Elig

b. Billroth I: (1)

c. Billroth II: (1)

d. Roux-en-Y gastrojejunostomy: (1)

e. Other pyloroplasty or antrectomy: (1) → C

f. Prior fundoplication: (1)

g. Other subtotal resection: (1) → C

h. Other gastric surgery *(specify):* (1)

____
other specify

13. Normal duodenum: Yes (1) → **14.** No (2)

(If no, check all that apply):

a. Duodenitis: (1)

b. Ulcer: (1)

c. Polyp(s): (1) → C

d. Mass: (1) → C

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

____
other specify

D. Histologic findings

14. Esophageal biopsy done: Yes (1) No (2) → **16.**

15. Esophageal histology normal: Yes (1) → **16.** No (2)

(If no, check all that apply):

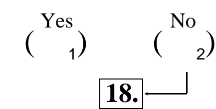
a. Esophagitis: (1)

b. Barrett's Esophagus: (1)

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

____
other specify

16. Gastric histology done: Yes (1) No (2) → **18.**



17. Gastric biopsy normal: Yes (1) → **18.** No (2)

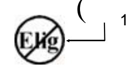
(If no, check all that apply):

a. Gastritis: (1)

b. Atrophic gastritis: (1) → C

c. Ulcer: (1)

d. Eosinophilic gastroenteritis: (1) → Elig



e. Fundic gland polyp: (1)

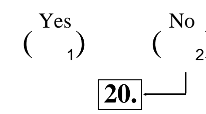
f. Adenomatous polyp: (1)

g. Helicobacter pylori infection: (1)

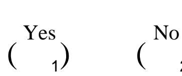
h. Other *(specify):* (1)

____
other specify

18. Duodenal biopsy done: Yes (1) No (2) → **20.**

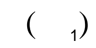


19. Duodenal histology normal: Yes (1) → **20.** No (2)

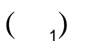


(If no, check all that apply):

a. Duodenitis: (1)



b. Ulcer: (1)



c. Celiac sprue: (1)

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

____
other specify

E. Other comments

20. Other comments concerning upper endoscopy procedure or results: Yes (1) No (2) → **21.**

a. Other comments:

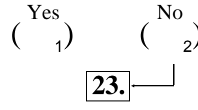
____

____

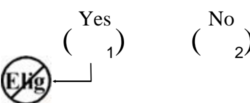
____

F. Eligibility check

21. Is this screening visit b: Yes (1) No (2) → **23.**



22. Was there any other endoscopic or histologic finding not recorded above that in the opinion of the Study Physician would characterize the patient as ineligible: Yes (1) → Elig No (2)



G. Administrative information

23. Study Physician PIN: ___ ___ ___

24. Study Physician signature:

____

25. Clinical Coordinator PIN: ___ ___ ___

26. Clinical Coordinator signature:

____

27. Date form reviewed: ___ ___ - ___ ___ ___ - ___ ___
day mon year

Keyed: (   )

Gastroparesis Registry 2

FD - Rome III Diagnostic Questionnaire

Purpose: To classify patients by the Rome III symptom-based diagnostic criteria into functional gastrointestinal disorders.
When: Screening visit s and follow-up visits f048, f096, f144, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-17.
Screening: The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-17. 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 2-17 and the Clinical Coordinator should complete section B.
Follow-up: Pages 2-17 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be reattached to pages 2-17 and the Clinical Coordinator should complete section B. Fill in item 4 with the date of the study visit.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____
2. Patient ID: ____ ____ ____ ____
3. Patient code: ____ ____ ____
4. Visit date: ____ ____-____ ____ ____-____ ____ (day, mon, year)
5. Visit code: ____ ____ ____ ____
6. Form & revision: f d 1
7. Study: GpR 2 5

B. Administrative information

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

8. Clinical Coordinator PIN: ____ ____ ____
9. Clinical Coordinator signature: ______________________
10. Date form reviewed: ____ ____-____ ____ ____-____ ____ (day, mon, year)

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Gastroparesis Registry 2

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

Items 1-10 are reserved for clinical center use.

Rome III Diagnostic Questionnaire

Instructions: The purpose of this survey is to learn more about the health problems that people sometimes have with their stomach and intestines. The questionnaire will take about 15 minutes to complete. To answer each question, circle the number to the left of the correct answer. You may find that you have not had any of the symptoms that we will ask you about. When this happens, you will be instructed to skip over the questions that do not apply to you. If you are not sure about an answer, or you cannot remember the answer to a question, just answer as best you can. It is easy to miss questions, so please check that you haven't left any out as you go.

For each question, circle only one answer.

Symptoms in the Esophagus

11. In the last 3 months, how often did you have a feeling of a lump, fullness, or something stuck in your throat?

0 Never . . . . → **If never, Skip to question 14**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

12. Have you had this feeling 6 months or longer?

0 No
1 Yes

13. Does this feeling occur between meals (when you are not eating)?

0 No
1 Yes

14. When you are eating or drinking, does it hurt to swallow?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

15. In the last 3 months, how often did you have pain or discomfort in the middle of your chest (not related to heart problems)?

0 Never . . . . → **If never, Skip to question 18**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

16. Have you had this chest pain 6 months or longer?

0 No
1 Yes

17. When you had your chest pain, how often did it feel like burning?

0 Never
1 Sometimes
2 Often
3 Most of the time
4 Always

18. In the last 3 months, how often did you have heartburn (a burning discomfort or burning pain in your chest)?

0 Never . . . . → **If never, Skip to question 20**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

19. Have you had this heartburn (burning pain or discomfort in the chest) 6 months or longer?

0 No
1 Yes

20. In the last 3 months, how often did food or drinks get stuck after swallowing or go down slowly through your chest?

0 Never . . . . → **If never, Skip to question 23**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

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Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

	Question		Response	
21.	Was the symptom of food sticking associated with heartburn?	0	Never or rarely	
		1	Sometimes	
		2	Often	
		3	Most of the time	
		4	Always	
22.	Have you had this problem 6 months or longer?	0	No	
		1	Yes	
23.	In the last 3 months, how often did you feel uncomfortably full after a regular-sized meal?	0	Never . . . . →	**If never, Skip to question 25**
		1	Less than one day a month	
		2	One day a month	
		3	Two to three days a month	
		4	One day a week	
		5	More than one day a week	
		6	Every day	
24.	Have you had this uncomfortable fullness after meals 6 months or longer?	0	No	
		1	Yes	
25.	In the last 3 months, how often were you unable to finish a regular-sized meal?	0	Never . . . . →	**If never, Skip to question 27**
		1	Less than one day a month	
		2	One day a month	
		3	Two to three days a month	
		4	One day a week	
		5	More than one day a week	
		6	Every day	
26.	Have you had this inability to finish regular-sized meals 6 months or longer?	0	No	
		1	Yes	

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Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

Symptoms in the Stomach and Intestines

27. In the last 3 months, how often did you have pain or burning in the middle of your abdomen, above your belly button but not in your chest?

0 Never . . . . → **If never, Skip to question 36**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

28. Have you had this pain or burning 6 months or longer?

0 No
1 Yes

29. Did this pain or burning occur and then completely disappear during the same day?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

30. Usually, how severe was the pain or burning in the middle of your abdomen, above your belly button?

0 Very mild
1 Mild
2 Moderate
3 Severe
4 Very severe

31. Was this pain or burning affected by eating?

0 Not affected by eating
1 Worse pain after eating
2 Less pain after eating

32. Was this pain or burning relieved by taking antacids?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

33. Did this pain or burning usually get better or stop after a bowel movement or passing gas?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

34. When this pain or burning started, did you usually have a change in the number of bowel movements (either more or fewer)?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

35. When this pain or burning started, did you usually have softer or harder stools?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

36. In the last 3 months, how often did you have bothersome nausea?

0 Never . . . . → **If never, Skip to question 38**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

37. Did this nausea start more than 6 months ago?

0 No
1 Yes

38. In the last 3 months, how often did you vomit?

0 Never . . . . → **If never, Skip to question 43**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

39. Have you had this vomiting 6 months or longer?

0 No
1 Yes

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

40. Did you make yourself vomit?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

41. Did you have vomiting in the last year that occurred in separate episodes of a few days and then stopped?

0 Never or rarely . . . . → **If never or rarely, Skip to question 43**
1 Sometimes
2 Often
3 Most of the time
4 Always

42. Did you have at least three episodes during the past year?

0 No
1 Yes

43. In the last 3 months, how often did food come back up into your mouth?

0 Never . . . . → **If never, Skip to question 49**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

44. Have you had this problem (food coming back up into your mouth) 6 months or longer?

0 No
1 Yes

45. When food came back up into your mouth, did it usually stay in your mouth for a while before you swallowed it or spit it out?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

46. Did you have retching (heaving) before food came into your mouth?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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47. When food came into your mouth, how often did you vomit or feel sick to your stomach?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

48. Did food stop coming back up into your mouth when it turned sour or acidic?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

49. In the last 3 months, how often did you experience bothersome belching?

0 Never . . . . → **If never, Skip to question 51**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

50. Did this bothersome belching start more than 6 months ago?

0 No
1 Yes

51. In the last 3 months, how often did you have discomfort or pain anywhere in your abdomen?

0 Never . . . . → **If never, Skip to question 62**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

52. Did you have pain only (not discomfort or a mixture of discomfort and pain)?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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53. For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other times?

0 No
1 Yes
2 Does not apply because I have had the change in life (menopause) or I am a male

54. When you had this pain, how often did it limit or restrict your daily activities (for example, work, household activities, and social events)?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

55. Have you had this discomfort or pain 6 months or longer?

0 No
1 Yes

56. How often did this discomfort or pain get better or stop after you had a bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

57. When this discomfort or pain started, did you have more frequent bowel movements?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

58. When this discomfort or pain started, did you have less frequent bowel movements?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

59. When this discomfort or pain started, were your stools (bowel movements) looser?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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60. When this discomfort or pain started, how often did you have harder stools?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

61. How often was this pain or discomfort relieved by moving or changing positions?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

62. In the last 3 months, how often did you have fewer than three bowel movements (0-2) a week?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

63. In the last 3 months, how often did you have hard or lumpy stools?*

0 Never or rarely
1 About 25% of the time
2 About 50% of the time
3 About 75% of the time
4 Always, 100% of the time

** Those who wish to use the new criteria for subclassifying IBS patients into subtypes based on stool consistency may substitute the following response scale in Questions 63 and 71:*

64. In the last 3 months, how often did you strain during bowel movements?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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65. In the last 3 months, how often did you have a feeling of incomplete emptying after bowel movements?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

66. In the last 3 months, how often did you have a sensation that the stool could not be passed, (i.e., was blocked), when having a bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

67. In the last 3 months, how often did you press on or around your bottom or remove stool in order to complete a bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

68. In the last 3 months, how often did you have difficulty relaxing or letting go to allow the stool to come out during a bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

69. Did any of the symptoms of constipation listed in questions 62-68 above begin more than 6 months ago?

0 No
1 Yes

70. In the last 3 months, how often did you have 4 or more bowel movements a day?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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71. In the last 3 months, how often did you have loose, mushy, or watery stools?*

0 Never or rarely .... → **If never or rarely, Skip to question 74**
1 About 25% of the time
2 About 50% of the time
3 About 75% of the time
4 Always, 100% of the time

** Those who wish to use the new criteria for subclassifying IBS patients into subtypes based on stool consistency may substitute the following response scale in Questions 63 and 71:*

72. In the last 3 months, were at least three-fourths (3/4) of your stools loose, mushy, or watery?

0 No
1 Yes

73. Did you begin having frequent loose, mushy, or watery stools more than 6 months ago?

0 No
1 Yes

74. In the last 3 months, how often did you have to rush to the toilet to have a bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

75. In the last 3 months, how often was there mucus or slime in your bowel movement?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

76. In the last 3 months, how often did you have bloating or distension?

0 Never .... → **If never, Skip to question 78**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

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77. Did your symptoms of bloating or distention begin more than 6 months ago?

0 No
1 Yes

Symptoms in the Gall Bladder or Pancreas

78. In the last 6 months, how often did you have steady pain in the middle or right side of your upper abdomen?

0 Never . . . . → **If never, Skip to question 85**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

79. Did this pain last 30 minutes or longer?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

80. Did this pain build up to a steady, severe level?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

81. Did this pain go away completely between episodes?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

82. Did this pain stop you from your usual activities, or cause you to see a doctor urgently or go to the emergency department?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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83. Have you had your gallbladder removed?

0 No . . . . → **If No, Skip to question 85**
1 Yes

84. How often have you had this pain since your gallbladder was removed?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

Symptoms in the Rectum or Anal Canal

85. In the last 3 months, how often have you accidentally leaked liquid or solid stool?

0 Never . . . . → **If never, Skip to question 88**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

86. In the last 3 months, when this leakage occurred, about what amount was leaked?

1 A small amount (staining only)
2 Moderate amount (more than staining, but less than a full bowel movement)
3 Large amount (a full bowel movement)

87. In the *last year*, when this leakage occurred, what was the composition of the leakage?

1 Liquid/mucus only
2 Stool only
3 Both liquid/mucus and stool

88. In the last 3 months, how often have you had aching, pain, or pressure in the anus or rectum when you were not having a bowel movement?

0 Never . . . . → **If never, Skip to question 92**
1 Less than one day a month
2 One day a month
3 Two to three days a month
4 One day a week
5 More than one day a week
6 Every day

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Visit code: __ __ __ __

89. How long did the aching, pain or pressure last?

1 From seconds to up to 20 minutes and disappeared completely
2 More than 20 minutes and up to several days or longer

90. Did the pain in your anus and rectum occur and then completely disappear during the same day?

0 No
1 Yes

91. Did the aching, pain, or pressure in the anal canal or rectum begin more than 6 months ago?

0 No
1 Yes

Other Questions

92. In the last 3 months, how often have you noticed blood in your stools?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

93. In the last 3 months, how often have you noticed black stools?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

94. In the last 3 months, how often have you vomited blood?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

95. Have you been told by your doctor that you are anemic (a low blood count or low iron)? (If female, *not* due to your menstrual period.)

0 No
1 Yes

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Visit code: __ __ __ __

96. In the last 3 months, how often have you taken your temperature and found it to be over 99 degrees Fahrenheit (38 degrees Centigrade) on different days?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

97. In the last 3 months, have you unintentionally lost over 10 pounds (4.5 kilograms)?

0 No
1 Yes

98. If you are over age 50, have you had a recent major change in bowel movements (change in frequency or consistency)?

0 No
1 Yes
2 Does not apply

99. Do you have a parent, brother, or sister who has (or had) one or more of the following:

a. Cancer of the esophagus, stomach or colon?

0 No
1 Yes

b. Ulcerative colitis or Crohn's disease?

0 No
1 Yes

c. Celiac disease?

0 No
1 Yes

100. In the past 3 months, how often did you have persistent or worsening hoarseness of the voice?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

101. In the past 3 months, how often did you have persistent or worsening neck or throat pain?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

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Affix label here

Pt ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

102. In the past 3 months, how often did you have chest pain on exertion, or chest pain related to heart problems?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

103. In the last 3 months, how often have you had difficulty swallowing?

0 Never or rarely
1 Sometimes
2 Often
3 Most of the time
4 Always

Return form to the Clinical Coordinator

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Gastroparesis Registry

FH - Follow-up Medical History

Purpose: To collect follow-up medical information about the patient.
When: f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, f192.
Administered by: Clinical Coordinator, reviewed by the Study Physician.
Respondent: Patient.
Instructions: Collect information by interview and/or 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: f ____ ____ ____

6. Form & revision: f h 3

7. Study: Gastroparesis Registry 1

B. Interval identification

8. Date of last Follow-up Medical History form *(if this is f016, then date of enrollment):*

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

C. Gastroparesis evaluation

9. Has the patient had an upper endoscopy since the date in item 8:

Yes (*1) No (2)

**Complete the EG form.*

10. Has the patient had a gastric emptying scintigraphy since the date in item 8:

Yes (*1) No (2)

**Complete the GE form.*

11. Since the date in item 8, which best describes the patient's symptoms of gastroparesis *(check all that apply):*

a. Nausea: (1)
b. Vomiting: (1)
c. Bloating: (1)
d. Early satiety *(a sense that your stomach is full after eating only a small amount of food):* (1)
e. Postprandial fullness *(a sense of fullness after the meal):* (1)
f. Abdominal pain: (1)
g. Diarrhea: (1)
h. Constipation: (1)
i. Anorexia: (1)
j. Weight loss: (1)
k. Weight gain: (1)
l. Gastroesophageal reflux symptoms such as heartburn: (1)
m. Problems with the management of diabetes or glycemic control: (1)
n. Other *(specify):* (1)

____
specify

o. None: (1) → **13.**

12. Select the predominant symptom listed in item 11 (a through n): ____

13. Since the date in item 8, has the patient had exacerbations of his/her symptoms of gastroparesis:

Yes (1) No (2) → **14.**

a. Number of Emergency room visits: ____ ____

14. Since the date in item 8, which best describes the nature of gastroparesis symptoms *(check only one):*

- Chronic, but stable symptoms (1)
- Chronic, but progressive worsening of symptoms (2)
- Chronic symptoms with periodic exacerbations (3)
- Cyclic pattern of exacerbations with periods of feeling well in between (4)
- Other *(specify):* (5)

______________________ specify

15. Since the date in item 8, which best describes the gastroparesis severity *(check only one):*

- **(Grade 1) Mild gastroparesis**: *Symptoms relatively easily controlled. Able to maintain weight and nutrition on a regular diet.* (1)
- **(Grade 2) Compensated gastroparesis**: *Moderate symptoms with only partial control with use of daily medications. Able to maintain nutrition with dietary adjustments.* (2)
- **(Grade 3) Gastroparesis with gastric failure**: *Refractory symptoms that are not controlled. Having ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via oral route.* (3)
- Other *(specify):* (4)

______________________ specify

D. Tobacco cigarette smoking history *(interview with patient)*

16. Since the date in item 8, have you smoked cigarettes regularly *("No" means less than 1 cigarette a day per week on average):*

Yes (1) No (2) → **19.**

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

___ # days

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

___ ___ ___ # cigarettes/day

E. Alcohol consumption (AUDIT-C) since the date in item 8 *(interview with patient)*

19. Since the date in item 8, how often have you had a drink containing alcohol *(check only one):*

- Never (0) → **22.**
- 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)

20. Since the date in item 8, how many drinks containing alcohol have you had on a typical day when you are drinking *(check only one):*

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

21. Since the date in item 8, how often have you had six or more drinks on one occasion *(check only one):*

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

F. Menstrual history

22. Is the patient female:

Yes (1) No (2) → **27.**

23. Characterize the menstrual history since the date in item 8 *(check only one):*

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

24. Did the patient have a hysterectomy:
Yes ($_1$) No ($_2$)

25. Is the patient postmenopausal: Yes ($_1$) No ($_2$) → **27.**

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

___ ___
age in years

G. Medical history

27. Is the patient diabetic: Yes ($_1$) No ($_2$) → **29.**

28. Describe the patient's glucose control since the date in item 8 *(interview with patient; check all that apply):*

- **a.** Well controlled ($_1$)
- **b.** Hypoglycemic events ($_1$)
- **c.** Glucose levels above 200 mg/dL ($_1$)
- **d.** Postprandial high glucose levels ($_1$)
- **e.** Postprandial low glucose levels ($_1$)

29. Since the date in item 8, has the patient 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.** Pyloric obstruction: ($_1$)
- **b.** Intestinal obstruction: ($_1$)
- **c.** Inflammatory bowel disease: ($_1$)
- **d.** Eosinophilic gastroenteritis: ($_1$)
- **e.** Acute renal failure: ($_1$)
- **f.** Acute liver failure: ($_1$)
- **g.** Advanced liver disease *(Child's B or C; a CPT score of 7 or greater):* ($_1$)
- **h.** Hepatitis B: ($_1$)
- **i.** Hepatitis C: ($_1$)
- **j.** Peptic ulcer disease: ($_1$)
- **k.** GERD: Gastroesophageal reflux disease: ($_1$)
- **l.** Interstitial cystitis: ($_1$)
- **m.** Bladder dysfunction: ($_1$)
- **n.** Diverticulosis: ($_1$)
- **o.** Endometriosis: ($_1$)
- **p.** Blood clots: ($_1$)
- **q.** Hemophilia *(bleeding disorder):* ($_1$)
- **r.** Systemic autoimmune disorder such as rheumatoid arthritis: ($_1$)
- **s.** Scleroderma: ($_1$)
- **t.** Thyroid disease *(hormonal abnormality):* ($_1$)
- **u.** Malignancy *(cancer):* ($_1$)
- **v.** Peripheral neuropathy: ($_1$)
- **w.** Migraine headaches: ($_1$)
- **x.** Seizure disorder or epilepsy: ($_1$)
- **y.** Chronic fatigue syndrome: ($_1$)
- **z.** Hypertension: ($_1$)
- **aa.** Coronary artery disease: ($_1$)
- **ab.** Cerebrovascular disease: ($_1$)
- **ac.** Hyperlipidemia *(high cholesterol, high triglycerides):* ($_1$)
- **ad.** Pancreatitis: ($_1$)
- **ae.** Cholelithiasis: ($_1$)
- **af.** Gallbladder disease including chronic cholecystitis, gallbladder dyskinesia: ($_1$)
- **ag.** Gout: ($_1$)
- **ah.** Polycystic ovary syndrome: ($_1$)
- **ai.** Dermatologic disorders: ($_1$)
- **aj.** Myopathy: ($_1$)
- **ak.** Fibromyalgia: ($_1$)
- **al.** Multiple sclerosis: ($_1$)
- **am.** Parkinson's disease: ($_1$)
- **an.** ALS: Amyotrophic lateral sclerosis: ($_1$)
- **ao.** Eating disorders *(anorexia, bulimia):* ($_1$)
- **ap.** Major depression: ($_1$)
- **aq.** Schizophrenia: ($_1$)
- **ar.** Bipolar disorder: ($_1$)

as. Obsessive compulsive disorder: (1)

at. Severe anxiety or personality disorder: (1)

au. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)

av. Systemic lupus erythematosus: (1)

aw. Collagen vascular disease: (1)

ax. Other unidentified systemic autoimmune disorder: (1)

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

____
specify

az. None of the above: (1)

30. Since the date in item 8, has the patient had any abdominal surgical procedures:

Yes (1) No (2) → **31.**

(Check all that apply):

a. Total gastric resection: (1)

b. Subtotal gastric resection *(vagotomy, pyloroplasty, antrectomy)*: (1)

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

d. Fundoplication for GERD: (1)

e. Gastrojejunostomy: (1)

f. Cholecystectomy: (1)

g. Percutaneous endoscopic gastrostomy (PEG): (1)

h. Jejunostomy: (1)

i. Other GI procedure *(specify)*: (1)

____
specify

31. Since the date in item 8, has the patient been hospitalized for gastroparesis:

Yes (1) No (2) → **34.**

32. Since the date in item 8, how many times has the patient been hospitalized for gastroparesis: ___ ___

33. Reason(s) for hospitalization *(check all that apply)*:

a. Intractable nausea and vomiting: (1)

b. Abdominal pain: (1)

c. Dehydration: (1)

d. Hyperglycemia: (1)

e. GI bleed: (1)

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

____
specify

H. Nutrition and gastric electrical stimulator (GES) use

34. What is the patient's current source of nutrition *(check all that apply)*:

a. Oral feeding: (1)

b. Enteral feeding: (1)

c. Parenteral feeding: (1)

35. Since the date in item 8, has the patient had a formal nutrition consult:

Yes (1) No (2)

36. Since the date in item 8, has the patient received total parenteral nutrition (TPN):

Yes (1) No (2)

37. Since the date in item 8, has the patient had any of the following placed:

	Yes	No
a. G tube:	(1)	(2)
b. J tube:	(1)	(2)
c. Central line/PICC:	(1)	(2)

38. Is a gastric electrical stimulator present:

Yes (1) No (2) → **39.**

a. Is gastric electrical stimulator currently turned on:

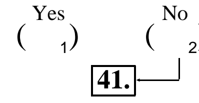
Yes (1) No (2)

39. Since the date in item 8, has the patient had any of the following removed:

	Yes	No
a. G tube:	(1)	(2)
b. J tube:	(1)	(2)
c. Central line/PICC:	(1)	(2)
d. Gastric stimulator:	(1)	(2)

I. Medication use

40. Since the date in item 8, has the patient added any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications:



(If yes or unsure, check all that apply):

a. Esomeprazole (Nexium):	(1)
b. Omeprazole (Prilosec, Zegerid):	(1)
c. Lansoprazole (Prevacid):	(1)
d. Pantoprazole (Protonix):	(1)
e. Rabeprazole (Aciphex):	(1)
f. Ranitidine (Zantac):	(1)
g. Famotidine (Pepcid):	(1)
h. Nizatidine (Axid):	(1)
i. Cimetidine (Tagamet):	(1)
j. Antacids, *(specify):*	(1)

____
specify

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

____
specify

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

____
specify

41. Since the date in item 8 has the patient added any prokinetic medications for gastroparesis:

Yes	No
(1)	(2) → **42.**

(If yes or unsure, check all that apply):

a. Azithromycin (Zithromax):	(1)
b. Bethanechol (Duvoid, Urecholine):	(1)
c. Botulinum toxin (Botox):	(1)
d. Cisapride (Propulsid):	(1)
e. Clarithromycin (Biaxin):	(1)
f. Domperidone (Motilium):	(1)
g. Erythromycin:	(1)
h. Metoclopramide (Reglan):	(1)
i. Tegaserod (Zelnorm):	(1)
j. Other *(specify):*	(1)

____
specify

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

____
specify

42. Since the date in item 8 has the patient used any of the following medications:

Yes ($_1$) No ($_2$) → **43.**

(If yes or unsure, check all that apply):

a. Prochlorperazine (Compazine): ($_1$)

b. Promethazine (Pentazine, Phenergan): ($_1$)

c. Trimethobenzamide (Benzacot, Stemetic, Tigan): ($_1$)

d. Meclizine (Antivert): ($_1$)

e. Ondansetron (Zofran): ($_1$)

f. Tropisetron (Navoban): ($_1$)

g. Granisetron (Kytril): ($_1$)

h. Palonosetron (Aloxi): ($_1$)

i. Dolasetron (Anzemet): ($_1$)

j. Lorazepam (Ativan): ($_1$)

k. Aprepitant (Emend): ($_1$)

l. Amitriptyline (Elavil): ($_1$)

m. Desipramine (Norpramin): ($_1$)

n. Nortriptyline (Aventyl, Pamelor): ($_1$)

o. Tetrahydrocannabinol (THC, marijuana): ($_1$)

p. Dronabinol (Marinol): ($_1$)

q. Mirtazapine (Remeron): ($_1$)

r. Bupropion (Wellbutrin): ($_1$)

s. Citalopram (Celexa): ($_1$)

t. Escitalopram (Lexapro): ($_1$)

u. Fluoxetine (Prozac): ($_1$)

v. Paroxetine (Paxil): ($_1$)

w. Sertraline (Zoloft): ($_1$)

x. Venlafaxine (Effexor): ($_1$)

y. Alprazolam (Xanax): ($_1$)

z. Buspirone (BuSpar): ($_1$)

aa. Chlordiazepoxide (Librax): ($_1$)

ab. Diazepam (Valium): ($_1$)

ac. Oxazepam (Serax): ($_1$)

ad. Clonazepam (Klonopin): ($_1$)

ae. Halazepam (Paxipam): ($_1$)

af. Meprobamate (Equanil, Meprospan): ($_1$)

ag. Quetiapine fumarate (Seroquel): ($_1$)

ah. Other *(specify):* ($_1$)

____
specify

ai. Other *(specify):* ($_1$)

____
specify

43. Since the date in item 8, has the patient used any antidiabetic medications:

Yes ($_1$) No ($_2$) → **44.**

(If yes or unsure, check all that apply):

a. Insulin: ($_1$)

b. Acarbose (Precose): ($_1$)

c. Acetohexamide (Dymelor): ($_1$)

d. Chlorpropamide (Diabinese): ($_1$)

e. Glimepiride (Amaryl): ($_1$)

f. Glipizide (Glucotrol): ($_1$)

g. Glyburide (Micronase, DiaBeta, Glynase): ($_1$)

h. Metformin (Glucophage): ($_1$)

i. Miglitol (Glycet): ($_1$)

j. Nateglinide (Starlix): ($_1$)

k. Pioglitazone (Actos): ($_1$)

l. Repaglinide (Prandin): ($_1$)

m. Rosiglitazone (Avandia): ($_1$)

n. Tolazamide (Tolinase): ($_1$)

o. Tolbutamide (Orinase): ($_1$)

p. Other *(specify):* ($_1$)

____
specify

44. Since the date in item 8, has the patient taken any alcohol abuse (dependance or withdrawal) medications:

Yes ($_1$) No ($_2$) → **45.**

(If yes or unsure, check all that apply):

a. Chlordiazepoxide (Librium): ($_1$)

b. Clorazepate dipotassium (Tranxene): ($_1$)

c. Diazepam (Valium): ($_1$)

d. Disulfiram (Antabuse): ($_1$)

e. Hydroxyzine pamoate (Vistaril): ($_1$)

f. Naltrexone hydrochloride (Revia): ($_1$)

g. Other *(specify):* ($_1$)

____
specify

45. Since the date in item 8, has the patient taken any pain relieving, analgesics, non-steroidal anti-inflammatory, or aspirin containing medications:

Yes ($_1$) No ($_2$) → **46.**

(If yes or unsure, check all that apply):

a. Acetaminophen (Tylenol): ($_1$)

b. Aspirin - 325 mg: ($_1$)

c. Celecoxib (Celebrex): ($_1$)

d. Ibuprofen (Advil, Motrin): ($_1$)

e. Indomethacin (Indocin): ($_1$)

f. Naproxen (Aleve, Naprosyn): ($_1$)

g. Other *(specify):* ($_1$)

____
specify

h. Other *(specify):* ($_1$)

____
specify

i. Other *(specify):* ($_1$)

____
specify

46. Since the date in item 8, has the patient used any narcotic pain medications:

Yes ($_1$) No ($_2$) → **48.**

(If yes, check all that apply):

a. Darvocet: ($_1$)

b. Fentanyl transdermal (Duragesic patch): ($_1$)

c. Esgic - Plus: ($_1$)

d. Fentanyl oral (Fertora, Actiq): ($_1$)

e. Fioricet: ($_1$)

f. Lorcet: ($_1$)

g. Lortab: ($_1$)

h. Methadone: ($_1$)

i. Norco: ($_1$)

j. Oxycodone: ($_1$)

k. Oxycontin: ($_1$)

l. Percocet: ($_1$)

m. Percodan: ($_1$)

n. Talacen: ($_1$)

o. Tylenol #3: ($_1$)

p. Tylenol #4: ($_1$)

q. Tylox: ($_1$)

r. Ultram (Tramadol HCl): ($_1$)

s. Ultracet: ($_1$)

t. Vicodin: ($_1$)

u. Wygesic: ($_1$)

v. Other *(specify):* ($_1$)

____
specify

47. Is the patient taking the narcotic pain medication for *(check all that apply)*

a. Abdominal pain: ($_1$)

b. Headache pain: ($_1$)

c. Back pain: ($_1$)

d. Other pain *(specify):* ($_1$)

____
specify

48. Since the date in item 8, has the patient taken any of the following neuropathic pain medications:

Yes (1) No (2) → **49.**

(If yes or unsure, check all that apply):

a. Duloxetine (Cymbalta): (1)

b. Gabapentin (Neurontin): (1)

c. Pregabalin (Lyrica): (1)

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

______________________ specify

49. Since the date in item 8, has the patient taken any antihyperlipidemic medications:

Yes (1) No (2) → **50.**

(If yes or unsure, check all that apply):

a. Atorvastatin (Lipitor): (1)

b. Colestipol hydrochloride (Colestid): (1)

c. Clofibrate (Abitrate, Atromid-S, Claripex, Novofibrate): (1)

d. Gemfibrozil (Gen-Fibro, Lopid): (1)

e. Fenofibrate (Tricor): (1)

f. Fluvastatin sodium (Lescol): (1)

g. Lovastatin (Mevacor): (1)

h. Nicotinic acid (Niaspan): (1)

i. Pravastatin sodium (Pravachol): (1)

j. Rosuvastatin (Crestor): (1)

k. Simvastatin (Zocor): (1)

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

______________________ specify

50. Since the date in item 8, has the patient taken any anticoagulant/antiplatelet medications:

Yes (1) No (2) → **51.**

(If yes or unsure, check all that apply):

a. Clopidogrel (Plavix): (1)

b. Dipyridamole (Persantine, Aggrenox): (1)

c. Heparin: (1)

d. Ticlopide (Ticlid): (1)

e. Warfarin (Coumadin): (1)

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

______________________ specify

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

______________________ specify

51. Since the date in item 8, has the patient taken any systemic corticosteroids:

Yes (1) No (2) → **52.**

(If yes or unsure, 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)

______________________ specify

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

______________________ specify

52. Since the date in item 8, has the patient taken any cardiovascular or antihypertensive medications:

Yes (1) No (2) → **53.**

(If yes or unsure, check all that apply):

a. Amiodarone (Pacerone): (1)

b. Amlodipine besylate (Norvasc): (1)

c. Atenolol (Tenormin): (1)

d. Benazepril (Lotensin): (1)

e. Captopril (Capoten): (1)

f. Clonidine (Catapres): (1)

g. Digoxin (Lanoxin): (1)

h. Diltiazem (Cardizem): (1)

i. Doxazosin (Cardura): (1)

j. Enalapril (Vasotec): (1)

k. Felodipine (Plendil): (1)

l. Furosemide (Lasix): (1)

m. Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)

n. Hydrochlorothiazide + triamterene (Dyazide): (1)

o. Lisinopril (Prinivil, Zestril): (1)

p. Losartan potassium (Cozaar): (1)

q. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)

r. Metoprolol (Lopressor): (1)

s. Nifedipine (Adalat, Procardia): (1)

t. Perhexiline maleate: (1)

u. Propranolol (Inderal): (1)

v. Quinapril (Accupril): (1)

w. Terazosin (Hytrin): (1)

x. Timolol maleate (Blocadren): (1)

y. Valsartan (Diovan): (1)

z. Verapamil (Calan): (1)

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

____
specify

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

____
specify

53. Since the date in item 8, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators:

Yes (1) No (2) → **54.**

(If yes or unsure, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

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

g. Levonorgestrel (Norplant): (1)

h. Medroxyprogesterone (Cycrin, Provera): (1)

i. Megestrol (Megace): (1)

j. Methyltestosterone (Android): (1)

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

l. Norethindrone (Micronor): (1)

m. Norgestrel (Ovrette): (1)

n. Oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (1)

o. Oxandrolone (Oxandrin): (1)

p. Oxymetholone (Anadrol): (1)

q. Progesterone (Prometrium): (1)

r. Raloxifene (Evista): (1)

s. Tamoxifen (Nolvadex): (1)

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

_______________ specify

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

_______________ specify

54. Since the date in item 8, has the patient taken any allergy or asthma medications:

Yes (1) No (2) → **55.**

(If yes or unsure, 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)

_______________ specify

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

_______________ specify

J. Alternative therapies

55. Since the date in item 8, has the patient used any alternative medicine or complementary medicine products or procedures for treatment of their symptoms related to gastroparesis *(e.g., bloating, nausea, vomiting, abdominal pain):*

Yes (1) No (2) → **56.**

(Check all that apply):

a. Acupuncture: (1)

b. Acupressure bands/bracelets: (1)

c. Reflexology: (1)

d. Hypnotherapy: (1)

e. Therapeutic Massage: (1)

f. Herbal supplements: (1)

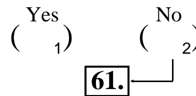
g. Probiotics: (1)

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

_______________ specify

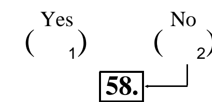
K. Change in treatment for gastroparesis

56. At this visit, are there changes being made in the patient's treatment for gastroparesis:



Yes (1) No (2) → **61.**

57. Were any medications stopped:

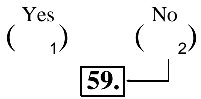


Yes (1) No (2) → **58.**

a. If yes, specify which medication(s):

_______________ specify

58. Were the dosages of any medications increased:

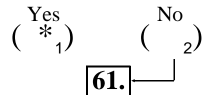


Yes (1) No (2) → **59.**

a. If yes, specify which medication(s):

_______________ specify

59. Were any additional treatments prescribed or ordered:



**These procedures should be captured on appropriate GpR forms EG, IE, etc.*

60. New additional treatment(s) *(check all that apply):*

a. Gastric electrical stimulation: (1)

b. Botox pylorus: (1)

c. Jejunostomy: (1)

d. Gastrostomy: (1)

e. Parenteral nutrition: (1)

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

____
specify

L. Administrative information

61. Study Physician PIN: ___ ___ ___

62. Study Physician signature:

____

63. Clinical Coordinator PIN: ___ ___ ___

64. Clinical Coordinator signature:

____

65. Date form reviewed:

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

Gastroparesis Registry 2

GD – Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM)

Purpose: To assess symptom severity in patients with gastroparesis.
When: Screening visit s, s2, and followup visits f024, f048, f072, f096, f120, f144, f168, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed forms.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A and attach a label to each of pages 2-3.
Screening: This form should be completed at the time of the gastric emptying scintigraphy whenever possible using the visit code s. This form will be completed a second time as part of the EGG and Nutrient Meal Test, using s2 for the visit code in item 5. 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 should complete section B.
Follow-up: Pages 2-3 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be attached to pages 2-3 and the Clinical Coordinator should complete section B. Fill in item 4 with the date the patient wrote in item 33. If the patient did not write in a date, use the date of the study visit.

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 *(use s2 when completed with ST form)*:

____ ____ ____ ____

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

7. Study: GpR 2 5

B. Administrative information

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

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

____

9. Date form reviewed:

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

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Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___ ___ ___

PAGI - SYM

Instructions: This questionnaire asks you about the severity of symptoms you may have related to your gastrointestinal problem. There are no right or wrong answers. Please answer each question as accurately as possible.

For each symptom, please circle the number that best describes how severe the symptom has been during the past 2 weeks. If you have not experienced this symptom, circle 0. If the symptom has been very mild, circle 1. If the symptom has been mild, circle 2. If it has been moderate, circle 3. If it has been severe, circle 4. If it has been very severe, circle 5. Please be sure to answer every question.

Please rate the severity of the following symptoms during the past 2 weeks.

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

		None	Very Mild	Mild	Moderate	Severe	Very Severe
10.	Nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4	5
11.	Retching (heaving as if to vomit, but nothing comes up)	0	1	2	3	4	5
12.	Vomiting	0	1	2	3	4	5
13.	Stomach fullness	0	1	2	3	4	5
14.	Not able to finish a normal-sized meal	0	1	2	3	4	5
15.	Feeling excessively full after meals	0	1	2	3	4	5
16.	Loss of appetite	0	1	2	3	4	5
17.	Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4	5
18.	Stomach or belly visibly larger	0	1	2	3	4	5
19.	Upper abdominal pain (above the navel)	0	1	2	3	4	5
20.	Upper abdominal discomfort (above the navel)	0	1	2	3	4	5

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Affix label here

Patient ID: ___ ___ ___ ___

Patient code: ___ ___ ___

Visit code: ___ ___ ___ ___

Please rate the severity of the following symptoms during the past 2 weeks.

		None	Very Mild	Mild	Moderate	Severe	Very Severe
21.	Lower abdominal pain (below the navel)	0	1	2	3	4	5
22.	Lower abdominal discomfort (below the navel)	0	1	2	3	4	5
23.	Heartburn during the day (burning pain rising in your chest or throat)	0	1	2	3	4	5
24.	Heartburn when lying down (burning pain rising in your chest or throat)	0	1	2	3	4	5
25.	Feeling of discomfort inside your chest during the day	0	1	2	3	4	5
26.	Feeling of discomfort inside your chest at night (during your sleep time)	0	1	2	3	4	5
27.	Regurgitation or reflux during the day (fluid or liquid from your stomach coming up into your throat)	0	1	2	3	4	5
28.	Regurgitation or reflux when lying down (fluid or liquid from your stomach coming up into your throat)	0	1	2	3	4	5
29.	Bitter, acid or sour taste in your mouth	0	1	2	3	4	5

In addition to the above symptoms, please rate the severity of the following two symptoms:

30.	Constipation	0	1	2	3	4	5
31.	Diarrhea	0	1	2	3	4	5

32. Of the symptoms on these 2 pages, which one is the predominant symptom (items 10-31):

_____ _____
10-31

33. Date form completed: _____ _____-_____ _____ _____-_____ _____
day mon year

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Gastroparesis Registry

GE - Gastric Emptying Scintigraphy Documentation

Purpose: To document the results of gastric emptying scintigraphy to determine patient eligibility and patient category during screening and to document gastric emptying scintigraphy findings, if any, during follow-up.

When: Screening visit b: Screening visit b: The baseline gastric emptying scintigraphy must have been performed at a GpCRC clinical center within 6 months of the registration date. **Follow-up visits**: The form should be completed at each follow-up visit. If patient has had a gastric emptying scintigraphy since the last study visit, results should be recorded on this form. If no results are available, complete items 1-8 and section D.

Administered by: Study Physician and Clinical Coordinator.

Instructions: The Study Physician should complete this form using the report generated by the gastric emptying scintigraphy. If STOP is reached for any item, then STOP filling out form and do not data enter the form. If C is checked for any item, further review is necessary to determine eligibility status. Information not included in the report should be gathered directly from the patient after the test if possible.

A. Identifying information

1. Center ID: ___ ___ ___ ___

2. Patient ID: ___ ___ ___ ___

3. Patient code: ___ ___ ___

4. Date of form: ___ ___-___ ___-___ ___ (day, mon, year)

5. Visit code: ___ ___ ___ ___

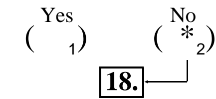
If report not associated with a visit, fill in "n."

6. Form & revision: g e 2

7. Study: Gastroparesis Registry 1

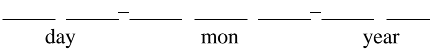
B. Gastric Emptying Scintigraphy Test

8. Are results from a gastric emptying scintigraphy available:

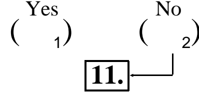


This test is required at screening visit b.

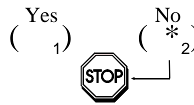
a. Date of gastric emptying scintigraphy:



9. Is this screening visit "b:"



10. Is this date within 6 months of registration:



Test must be rescheduled.

11. Meal given for test

Egg Beaters: (1)

Generic low-fat egg whites: (2)

Other *(specify)* (* 3) → C

____
specify

Caution: Test may have to be repeated depending on the meal.

12. Amount of meal consumed

a. Meal *(check only one):*

100%	(1)
90%	(2)
75%	(3)
50%	(4)
33%	(5)
25%	(6)
10%	(7)
0%	(8)
Unknown	(9)

b. Water *(check only one):*

100%	(1)
90%	(2)
75%	(3)
50%	(4)
33%	(5)
25%	(6)
10%	(7)
0%	(8)
Unknown	(9)

13. Percent gastric retention
Analysis is performed using the geometric mean of the anterior and posterior images for each time point which are then corrected for decay. Results expressed as percent remaining in the stomach.

a. 0 minutes: ___ ___ ___ • ___ %

b. 30 minutes*: ___ ___ ___ • ___ %

c. 1 hour: ___ ___ ___ • ___ %

d. 2 hours: ___ ___ ___ • ___ %

e. 3 hours*: ___ ___ ___ • ___ %

f. 4 hours: ___ ___ ___ • ___ %

**The 30 minute and 3 hour time points are optional, but should be obtained if possible. The 0 minutes, 1, 2, and 4 hour time points are required.*

14. Interpretation of gastric emptying scintigraphy:

____

____

____

15. Comments on the gastric emptying scintigraphy:

____

____

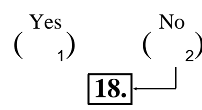
____

____

C. Eligibility check

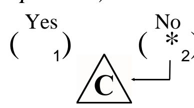
16. Is this screening visit b:

Yes (1) No (2)



17. Do the results documented from the gastric emptying scintigraphy qualify this patient for enrollment in Gastroparesis Registry *(Patients must have either or both abnormal 2 hour (>60% retention) and 4 hour (>10% retention) gastric emptying to be classified as definite gastroparesis):*

Yes (1) No (* 2)



**Patient must have symptoms of gastroparesis of at least 12 weeks duration to be eligible for the Registry.*

D. Administrative information

18. Study Physician PIN: ___ ___ ___

19. Study Physician signature:

____

20. Clinical Coordinator PIN: ___ ___ ___

21. Clinical Coordinator signature:

____

22. Date reviewed: ___ ___ – ___ ___ ___ – ___ ___
day mon year

Gastroparesis Registry

ID – Investigator Derived Independent Outcome Measure Scores (IDIOMS)

Purpose: To obtain information from the Study Physician regarding the current state of the patient's gastroparesis.
When: Screening visit b and follow-up visits, f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192.
Respondent: Study Physician.
Instructions: Complete this form based on the patient's condition since the last screening or follow-up visit.

A. Center, patient, and visit identification

1. Center ID: ___ ___ ___ ___
2. Patient ID: ___ ___ ___ ___
3. Patient code: ___ ___ ___
4. Date of visit *(date Study Physician completed the form)*:

   ___ ___-___ ___ ___-___ ___
   day mon year

5. Visit code: ___ ___ ___ ___
6. Form & revision: **i** **d** **1**
7. Study: Gastroparesis Registry 1

B. Administrative information

8. Study Physician PIN: ___ ___ ___
9. Study Physician signature:

   ____

10. Date form reviewed:

   ___ ___-___ ___ ___-___ ___
   day mon year

ID - Investigator Derived Independent Outcome Measure Scores (IDIOMS)

11. Severity of Illness (SOI):

Mild symptoms			**Moderate symptoms**		**Severe symptoms**			**Very severe symptoms**	
1	2	3	4	5	6	7	8	9	10

12. Other Significant Illnesses (OSI):

GI organ involve-ment only	**GI organ involvement and at most, mild other disease**		**GI and 1 other organ system involved and moderate other disease**		**GI, and 2 other organ systems involved, and severe other disease**			**GI and 3 or more organ systems involved, and severe other disease**	
1	2	3	4	5	6	7	8	9	10

13. Intensity of Services (IOS):

Medicines only			**Medicines and home health services**		**Medicines, home health services, and 1 inpatient hospitalization in the last 12 months**			**Medicines, home health services, and multiple inpatient hospitalizations in the last 12 months**	
1	2	3	4	5	6	7	8	9	10

14. Total score *(the total score is the sum of the individual scores for items 11 through 13)*:

___ ___

15. Comments:

____

____

____

____

Gastroparesis Registry

IE - Interim Event Report

Purpose: To document any event (e.g., symptom exacerbations, Emergency Room visits, upper endoscopy or gastric emptying scintigraphy complications, surgical interventions for symptom management, and complications of these interventions) that occurs after registration and impacts the patient's participation in the Gastroparesis Registry and is not recorded on another Gastroparesis Registry form.

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

Administered by: Study Physician and Clinical Coordinator.

Instructions: Complete and key this form for any event that meets the criteria above. The short name (item 17) and the severity code (item 18) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v3.0 (CTCAE). The CTCAE document is available at www.gpcrc.us; click on Documents. Fax the DCC (Attention: Laura Miriel) a copy of this form if severity grade is 3 or higher (Fax 410-955-0932).

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

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: n ____ ____ ____

6. Form & revision: i e 1

7. Study: Gastroparesis Registry 1

B. Visit interval identification

8. Most recently completed study visit (screening or follow-up)

a. Date: ____ ____–____ ____ ____–____ ____ (day, mon, year)

b. Visit code: ____ ____ ____ ____

C. Patient information

9. Gender:

Male (1)

Female (2)

10. Age at time of event: ____ ____ years

D. Event description

11. Date event started: ____ ____–____ ____ ____–____ ____ (day, mon, year)

12. Was the event due to gastroparesis symptom exacerbation or increased severity of gastroparesis symptoms, such as excessive nausea, vomiting, or pain:

Yes (1) No (2)

13. What was the event due to *(check all that apply):*

a. Dehydration: (1)

b. Hyperglycemia: (1)

c. Hypoglycemia: (1)

d. Malnutrition: (1)

e. Side effects of drugs used as standard of care: (1)

f. Failure of medical therapy: (1)

g. Ran out of medication: (1)

h. Worsening of co-morbid illness: (1)

i. Study procedure related event: (1)

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

____

____

14. Did the event lead to *(check all that apply):*

a. Emergency Room visit: (1)

b. Hospitalization: (1)

c. Infectious episode: (1)

d. G tube placement: (1)

e. J tube placement: (1)

f. Central line/PICC: (1)

g. Gastric electric stimulator: (1)

h. Other surgical intervention(s) *(specify):* (1)

____

____

i. Complications due to surgical interventions to better control the gastroparesis symptoms *(specify):* (1)

____

____

j. Office visit: (1)

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

____

____

15. Describe event:

____

____

____

____

____

____

16. As a result of this event, are there any changes in the patient's treatment for gastroparesis:

Yes (1) No (2)

If yes, specify:

____

____

____

____

17. Short name for event if applicable *(short names for AEs are listed in the CTCAE v3.0 document available at www.gpcrc.us; click on Documents):*

Not applicable (0)

____

____

18. Severity grade *(severity grades are listed in the CTCAE v3.0 document available at www.gpcrc.us; click on Documents):*

Not applicable (0)

Grade 1 - Mild (1)

Grade 2 - Moderate (2)

Grade 3 - Severe (3)

Grade 4 - Life threatening or disabling (4)

Grade 5 - Death (* 5)

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

19. Date event resolved *(enter "n" if event is not yet resolved):*

___ ___-___ ___ ___-___ ___
day mon year

20. What action was taken:

____

____

____

____

____

____

21. Other comments on event:

____

____

____

____

____

____

E. Administrative information

22. Clinical Coordinator PIN: ____ ____ ____

23. Clinical Coordinator signature:

____

24. Study Physician PIN: ____ ____ ____

25. Study Physician signature:

____

26. Date form reviewed:

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

Key this form. If the severity grade is 3 or higher, fax the form to the DCC (Attention: Laura Miriel) for review by Linda Lee, the Safety Officer. Reports will be distributed for further review by the Steering Committee and Data and Safety Monitoring Board.

Gastroparesis Registry

LR - Laboratory Results

Purpose: To record archival and current laboratory test results for tests done during screening and follow-up.

When: Required at screening visit b and as needed at follow-up visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Laboratory test results may be obtained from chart review. Record the earliest blood draw date if there are multiple blood draws. Complete tests as needed (repeat test if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Please note that the units 10^3 cells/mL, 1000 cells/mL, and 10^9/L are equivalent. Call the DCC if you have a question about conversion or how to record a value. If (Elig) is reached in item 31 or in item 45, the patient is NOT eligible and cannot enroll in the Gastroparesis Registry. The form should not be keyed to the data system. Staple the lab report to the back of this form. If your lab reports values electronically, print a copy of the results and staple the report to the back of this form.

A. Center, patient, and visit identification

1. Center ID: ___ ___ ___ ___

2. Patient ID: ___ ___ ___ ___

3. Patient code: ___ ___ ___

4. Date of visit *(date form was initiated)*:

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

5. Visit code: ___ ___ ___ ___

6. Form & revision: 1 r 1

7. Study: Gastroparesis Registry 1

B. Etiologic lab tests

8. Are lab results available for ANA, Scl-70, CRP, and SPEP at this visit:

Yes (1) No (2) → **14.**

These tests are required at screening visit b.

9. Date of blood draw for ANA, Scl-70, CRP, and SPEP:

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

Record the earliest blood draw date if there are multiple blood draws. Date must be within the required time window: within one year of the registration or in the time window for the follow-up visit (check the patient's Registry visit time window guide). These tests are optional during follow-up visits.

10. Antinuclear antibody (ANA):

Positive (1)
Negative (2) → **11.**

a. If positive, titer of ANA:

1: ___ ___ ___ ___

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

11. Scleroderma antibody (Scl-70):

Positive (1)
Negative (2) → **12.**

a. If positive, titer of Scl-70:

1: ___ ___ ___

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

12. C-reactive protein (CRP) *(if result is reported as normal but below your lab's detectable level, enter the cutoff value for your lab's detectable level)*:

___ ___ ___ • ___ ___ mg/dL

If units reported are mg/L, divide by 10 to convert to mg/dL.

13. Serum protein electrophoresis (SPEP):

a. Albumin: ___ ___ • ___ g/dL

b. Alpha-1-Globulin: ___ • ___ g/dL

c. Alpha-2-Globulin: ___ • ___ g/dL

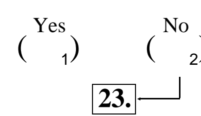
d. Beta-Globulin: ___ • ___ g/dL

e. Gamma-Globulin: ___ • ___ g/dL

f. SPEP total protein: ___ ___ • ___ g/dL

C. Hematology

14. Are lab results available for hematology panel at this visit:



Yes (1) No (2) → **23.**

These tests are required at screening visit b.

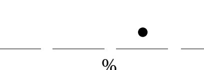
15. Date of blood draw for hematology panel:

___ ___ – ___ ___ – ___ ___
day mon year

Record the earliest blood draw date if there are multiple blood draws. Date must be within the required time window: within 16 weeks of registration or in the time window for the follow-up visit (check the patient's Registry visit time window guide). These tests are optional during follow-up visits.

16. Hemoglobin: ___ ___ • ___ g/dL

17. Hematocrit: ___ ___ • ___ %



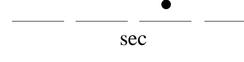
18. Erythrocyte sedimentation rate ___ ___ ___ mm/hr

19. White blood cell count (WBC):

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

20. Platelet count: ___ ___ ___ , ___ ___ ___ cells/ μL

21. Prothrombin time (PT): ___ ___ • ___ sec



a. International Normalized Ratio (INR):

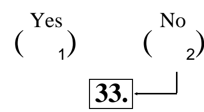
___ • ___ ___

22. Partial thromboplastin time (PTT):

___ ___ • ___ sec

D. Chemistries and HbA1c

23. Are results available for chemistry panel at this visit:



Yes (1) No (2) → **33.**

These tests are required at screening visit b.

24. Date of blood draw for chemistries:

___ ___ – ___ ___ – ___ ___
day mon year

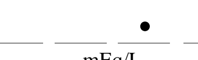
Record the earliest blood draw date if there are multiple blood draws. Date must be within the required time window: within 16 weeks of registration or in the time window for the follow-up visit (check the patient's Registry visit time window guide). These tests are optional during follow-up visits.

25. Sodium: ___ ___ ___ mEq/L

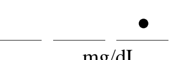
26. Potassium: ___ ___ • ___ mEq/L

27. Chloride: ___ ___ ___ mEq/L

28. Carbon dioxide: ___ ___ • ___ mEq/L

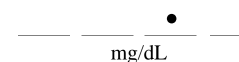


29. Calcium: ___ ___ • ___ mg/dL

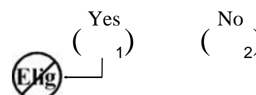


30. Blood urea nitrogen (BUN): ___ ___ mg/dL

31. Creatinine: ___ ___ • ___ mg/dL



a. Is this screening visit b and creatinine greater than 3 mg/dL:



Yes (1) → Elig No (2)

If Yes, the patient is ineligible and cannot be enrolled in the Gastroparesis Registry. This form should not be keyed to the data system but retained by the study site. Refer to SOP I regarding repeating this test.

32. Serum glucose: ___ ___ ___ mg/dL

33. Is HbA1c result available at this visit:

Yes ($_1$) No (* $_2$) → **36.**

** This test is required at screening visit b and at each follow-up visit for diabetic patients. (Please record any available HbA1c results for non-diabetic patients).*

34. Date of blood draw for HbA1c:

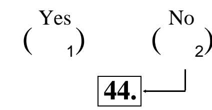
____ - ____ ____ ____ - ____ ____
day mon year

Date must be within the required time window: within 16 weeks of registration or in the time window for the follow- up visit (check the patient's Registry visit time window guide). This test is optional during follow-up visits.

35. HbA1c: ___ ___ • ___ %

E. Hepatic panel

36. Are hepatic panel results available at this visit:



Yes ($_1$) No ($_2$) → **44.**

These tests are required at screening visit b.

37. Date of blood draw for hepatic panel:

____ - ____ ____ ____ - ____ ____
day mon year

Record the earliest blood draw date if there are multiple blood draws. Date must be within the required time window: within 16 weeks of registration or in the time window for the follow- up visit (check the patient's Registry visit time window guide). These tests are optional during follow-up visits.

38. Bilirubin (total): ___ ___ • ___ mg/dL

39. Aspartate aminotransferase (AST): ___ ___ ___ U/L

40. Alanine aminotransferase (ALT): ___ ___ ___ U/L

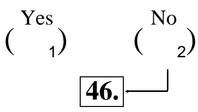
41. Alkaline phosphatase ___ ___ ___ U/L

42. Albumin: ___ ___ • ___ g/dL

43. Total protein: ___ ___ • ___ g/dL

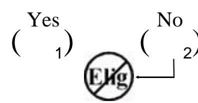
F. Eligibility check

44. Is this screening visit b:



Yes ($_1$) No ($_2$) → **46.**

45. Are all required screening lab results completed on this form:



Yes ($_1$) No ($_2$) → Elig

If No, the patient is ineligible and cannot be enrolled in the Gastroparesis Registry.

G. Administrative information

46. Study Physician PIN: ___ ___ ___

47. Study Physician signature:

____

48. Clinical Coordinator PIN: ___ ___ ___

49. Clinical Coordinator signature:

____

50. Date form reviewed:

____ - ____ ____ ____ - ____ ____
day mon year

Gastroparesis Registry

PE - Physical Examination

Purpose: Record detailed physical exam findings.
When: Screening visit b and follow- up visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient.
Instructions: Details of the protocol for height, weight, waist and hip measurements are found in Gastroparesis Registry SOP, Part I. In brief: Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Measure the hips at the fullest part.

A. Center, patient, and visit identification

1. Center ID: ___ ___ ___ ___

2. Patient ID: ___ ___ ___ ___

3. Patient code: ___ ___ ___

4. Visit date: ___ ___ – ___ ___ – ___ ___
day mon year

5. Visit code: ___ ___ ___ ___

6. Form & revision: p e 1

7. Study: Gastroparesis Registry 1

B. Measurements

8. Height *(shoes off)*

a. Height: ___ ___ ___ ___ • ___

b. Units:
Inches (1)
Centimeters (2)

9. Weight *(shoes off)*

a. Weight: ___ ___ ___ ___ • ___

b. Units:
Pounds (1)
Kilograms (2)

10. Waist *(standing, at midpoint between highest point of iliac crest and lowest part of costal margin)*

a. Circumference: ___ ___ ___ ___ • ___

b. Units:
Inches (1)
Centimeters (2)

11. Hip *(standing, at fullest part of the hips)*

a. Circumference: ___ ___ ___ ___ • ___

b. Units:
Inches (1)
Centimeters (2)

12. Temperature *(oral)*

a. Degrees: ___ ___ ___ ___ • ___

b. Scale:
Fahrenheit (1)
Centigrade (2)

13. Blood pressure

a. Systolic: ___ ___ ___ mmHg

b. Diastolic: ___ ___ ___ mmHg

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

15. Respiratory rate: ___ ___ breaths/minute

C. Examination findings

16. Chest and lungs:

Normal (1)

Abnormal (2) → **17.**

specify

17. Heart:

Normal (1)

Abnormal (2) → **18.**

specify

18. Abdomen:

Normal (1)

Abnormal (2) → **20.**

19. Abdomen abnormality
(check all that apply)

a. Distention: (1)

b. Tympany: (1)

c. Succussion splash: (1)

d. Tenderness: (1)

e. Organomegaly: (1)

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

specify

20. Liver and spleen:

Normal (1)

Abnormal (2) → **21.**

specify

21. Nervous system:

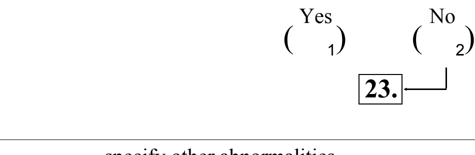
Not performed (0) → **22.**

Normal (1) → **22.**

Abnormal (2)

specify

22. Other abnormalities noted:



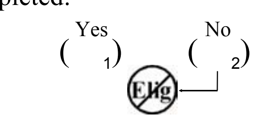
specify other abnormalities

D. Eligibility check

23. Is this a screening visit:

Yes (1) No (2) → **25.**

24. Are all items on form completed:



E. 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

Gastroparesis Registry 2 — PI – Brief Pain Inventory

Purpose: To assess the severity and impact on daily functions of the patient's pain.
When: Screening visit s and follow-up visits f048, f096, f144, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed forms.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A and attach a pre-printed patient label to each of pages 2-4. **Screening:** The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-4. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B.
Follow-up: Pages 2-4 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be attached to pages 2-4 and the Clinical Coordinator should complete section B. Fill in item 4 with the date the patient wrote in item 18. If the patient did not write in a date, use the date of the study visit.

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: _____ _____ _____ _____
6. Form & revision: **p** **i** **1**
7. Study: GpR 2 5

B. Administrative information

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

8. Clinical Coordinator
   a. PIN: _____ _____ _____
   b. Signature: ______________________________
9. Date form reviewed:
   _____ _____-_____ _____ _____-_____ _____
   day mon year

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Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

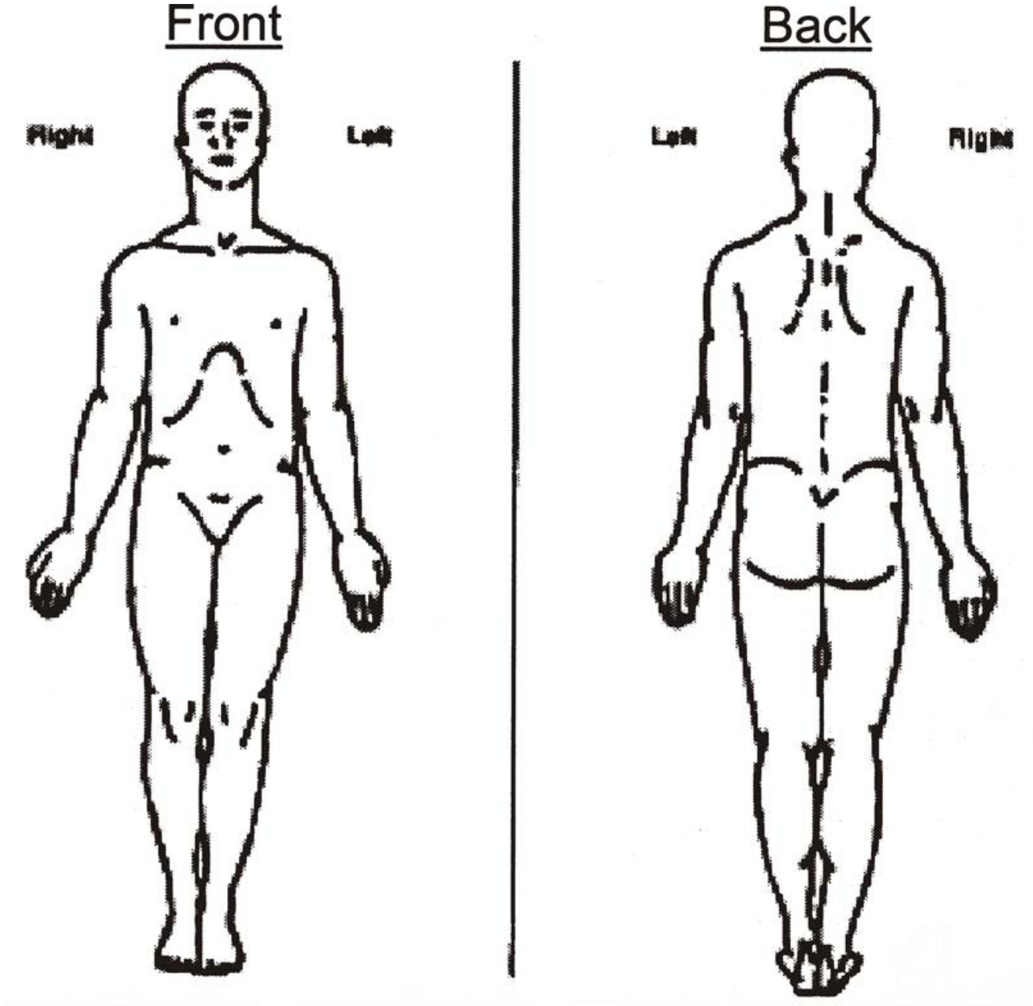
(Items 1-9 are reserved for clinical center use.)

Brief Pain Inventory

10. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No ➔ *If No, skip to question 18*

On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



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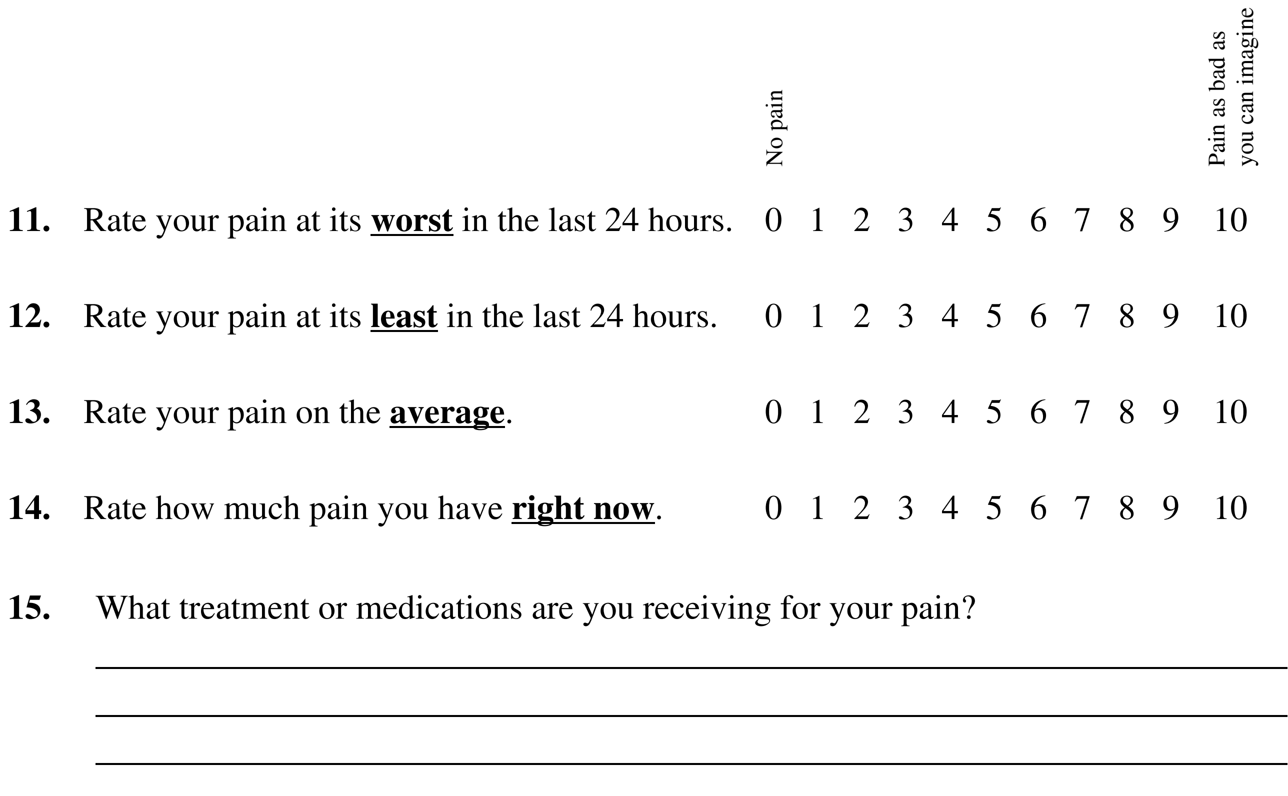
Affix label here	
Patient ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

Please circle the number that best describes your pain with “**0**" being “**No pain**” and “**10**" being “**Pain bad as you can imagine**”.



		No pain										Pain as bad as you can imagine
11.	Rate your pain at its **worst** in the last 24 hours.	0	1	2	3	4	5	6	7	8	9	10
12.	Rate your pain at its **least** in the last 24 hours.	0	1	2	3	4	5	6	7	8	9	10
13.	Rate your pain on the **average**.	0	1	2	3	4	5	6	7	8	9	10
14.	Rate how much pain you have **right now**.	0	1	2	3	4	5	6	7	8	9	10

15. What treatment or medications are you receiving for your pain?

____

____

____

If none, go to item 17.

16. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the percentage that most shows how much **relief** you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

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

17. Using the scale with "**0**" being "**Does not interfere**" and "**10**" being "**Interferes completely**", circle the number that describes how pain during the past 24 hours has interfered with your:

		Does not interfere										Completely interferes
a.	General activity	0	1	2	3	4	5	6	7	8	9	10
b.	Mood	0	1	2	3	4	5	6	7	8	9	10
c.	Walking ability	0	1	2	3	4	5	6	7	8	9	10
d.	Normal Work (includes both work outside the home and housework)	0	1	2	3	4	5	6	7	8	9	10
e.	Relations with other people	0	1	2	3	4	5	6	7	8	9	10
f.	Sleep	0	1	2	3	4	5	6	7	8	9	10
g.	Enjoyment of life	0	1	2	3	4	5	6	7	8	9	10

18. Date form completed: _____ _____-_____ _____ _____-_____ _____

day mon year

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Gastroparesis Registry 2

RG - Registration

Purpose: To register patients as candidates for enrollment in the Gastroparesis Registry 2 (GpR 2) study and to assign a patient ID number. This is the first form completed for a GpR 2 patient. The Registration Form must be the first form keyed, before any other GpR 2 forms.

When: At first screening visit (s).

Administered by: Clinical Coordinator.

Respondent: Patient.

Instructions: Use Flash Cards as instructed. Do not assign an ID if patient has previously been assigned an ID for a GpCRC study. If a STOP is reached, do not key the form. If an eligibility item is checked in item 8a, the patient is ineligible for GpR 2 and a patient ID should not be assigned 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: GpR 2 5

B. Consent and screen check

8. Has the patient signed the Gastroparesis Registry 2 informed consent statement:

Yes (1) No (* 2) → STOP

* *Patient must sign the consent prior to continuing with screening.*

a. Is the patient allergic to eggs:

Yes (* 1) → Elig No (2)

* *Do not key the form, the patient is ineligible for GpR 2.*

C. Information about patient

9. Date of birth:

___ ___–___ ___ ___–___ ___ ___ ___
day month year

Record 4-digit year for date of birth.

10. Age at last birthday *(patient must be 18 or older):*

___ ___ years

11. Gender:

- Male (1)
- Female (2)

12. Ethnic category *(show the patient Flash Card #1 and ask him/her to pick the category that describes him/her best; check only one):*

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

13. Racial category *(show the patient Flash Card #2 and him/her to pick the category or categories that describes him/her best; check all that apply)*

- **a.** American Indian or Alaska Native: (1)
- **b.** Asian: (1)
- **c.** Black or African American: (1)
- **d.** Native Hawaiian or other Pacific Islander: (1)
- **e.** White: (1)
- **f.** Patient refused: (1)

14. Highest educational level achieved by patient *(show the patient Flash Card #3 and ask him/her to pick the category that describes him/her best; 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)

15. Which of the following categories best characterizes the patient's occupational history *(show the patient Flash Card #4 and ask him/her to pick the category that describes him/her best; check only one):*

Never employed	(0)
Laborer	(1)
Clerical	(2)
Professional	(3)
Homemaker	(4)
Other, *(specify):*	(5)

____
specify

16. Marital status of the patient *(show the patient Flash Card #5 and ask him/her to pick the category that describes him/her best; check only one):*

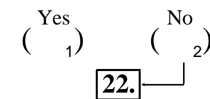
Single, never married	(1)
Married or living in marriage-like relationship	(2)
Separated, divorced, or annulled	(3)
Widowed	(4)

17. Combined annual income before taxes of all members of patient's household *(show the patient Flash Card #6 and ask him/her to pick the category that describes his/her 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)

D. Previous registration in a GpCRC study

18. Has the patient ever been assigned an ID number in a GpCRC study:



19. In which GpCRC studies has the patient previously been registered *(check all that apply)*

a. Registry:	(1)
b. NORIG:	(1)
c. GLUMIT-DG:	(1)
d. APRON:	(1)
e. Other, *(specify):*	(1)

____
specify

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

____ ____ ____ ____

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

____ ____ ____

23.

F. ID assignment

(If a STOP or Eligibility 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 GpCRC study, a new ID number should not be assigned.)

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

CCCC ####, zzz

G. Administrative information

23. Clinical Coordinator PIN: ____ ____ ____

24. Clinical Coordinator signature:

____

25. Date form reviewed:

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

Gastroparesis Registry 2

SE - State-Trait Anxiety Inventory (Self-Evaluation Questionnaire)

Purpose: To collect data on the psychosocial aspects of gastroparesis in the Gastroparesis Registry 2 study.
When: At screening visit s and follow-up visits f024, f048, f096, f120, f144, f168, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-4 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. Pages 1 and 4 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B. **Scoring:** The Y-1 and Y-2 scores should be calculated using the scoring key on page 4. **Only the items on page 1 are keyed to the GpR 2 data system**. Staple pages 1-4 together at the close of the assessment.

A. Clinic, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date:

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: s e 1

7. Study: GpR 2 5

B. Administrative information
(To be completed by clinical center staff after questionnaire is completed.)

8. Scoring

a. Form Y-1 *(sum of weights for items 1-20)*

____ ____
(20-80)

b. Form Y-2 *(sum of weights for items 21-40)*

____ ____
(20-80)

9. Clinical Coordinator

a. PIN: ____ ____ ____

b. Signature:

____

10. Date form reviewed:

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

Self-Evaluation Questionnaire
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Affix label here	
Pt ID:	__ __ __ __
Patient code:	__ __ __
Visit code:	__ __ __ __

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-1

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feeling best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	**1**	**2**	**3**	**4**
2. I feel secure	**1**	**2**	**3**	**4**
3. I am tense	**1**	**2**	**3**	**4**
4. I am strained	**1**	**2**	**3**	**4**
5. I feel at ease	**1**	**2**	**3**	**4**
6. I feel upset	**1**	**2**	**3**	**4**
7. I am presently worrying over possible misfortunes	**1**	**2**	**3**	**4**
8. I feel satisfied	**1**	**2**	**3**	**4**
9. I feel frightened	**1**	**2**	**3**	**4**
10. I feel comfortable	**1**	**2**	**3**	**4**
11. I feel self-confident	**1**	**2**	**3**	**4**
12. I feel nervous	**1**	**2**	**3**	**4**
13. I am jittery	**1**	**2**	**3**	**4**
14. I feel indecisive	**1**	**2**	**3**	**4**
15. I am relaxed	**1**	**2**	**3**	**4**
16. I feel content	**1**	**2**	**3**	**4**
17. I am worried	**1**	**2**	**3**	**4**
18. I feel confused	**1**	**2**	**3**	**4**
19. I feel steady	**1**	**2**	**3**	**4**
20. I feel pleasant	**1**	**2**	**3**	**4**

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

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-2

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	**1**	**2**	**3**	**4**
22. I feel nervous and restless	**1**	**2**	**3**	**4**
23. I feel satisfied with myself	**1**	**2**	**3**	**4**
24. I wish I could be as happy as others seem to be	**1**	**2**	**3**	**4**
25. I feel like a failure	**1**	**2**	**3**	**4**
26. I feel rested	**1**	**2**	**3**	**4**
27. I am "calm, cool, and collected"	**1**	**2**	**3**	**4**
28. I feel that difficulties are piling up so that I cannot overcome them	**1**	**2**	**3**	**4**
29. I worry too much over something that really doesn't matter	**1**	**2**	**3**	**4**
30. I am happy	**1**	**2**	**3**	**4**
31. I have disturbing thoughts	**1**	**2**	**3**	**4**
32. I lack self-confidence	**1**	**2**	**3**	**4**
33. I feel secure	**1**	**2**	**3**	**4**
34. I make decisions easily	**1**	**2**	**3**	**4**
35. I feel inadequate	**1**	**2**	**3**	**4**
36. I am content	**1**	**2**	**3**	**4**
37. Some unimportant thought runs through my mind and bothers me	**1**	**2**	**3**	**4**
38. I take disappointments so keenly that I can't put them out of my mind	**1**	**2**	**3**	**4**
39. I am a steady person	**1**	**2**	**3**	**4**
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	**1**	**2**	**3**	**4**

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

SELF-EVALUATION QUESTIONNAIRE SCORING KEY (Form Y-1, Y-2)

DIRECTIONS:

To use this stencil, fold this sheet in half and line up with the appropriate test page, either Form Y-1 or Form Y-2. Simply total the scoring **weights** shown on the stencil for each response category. For example, for question #1, if the respondent marked 3, then the **weight** would be 2.

Form Y-1

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1.	4	3	2	1
2.	4	3	2	1
3.	1	2	3	4
4.	1	2	3	4
5.	4	3	2	1
6.	1	2	3	4
7.	1	2	3	4
8.	4	3	2	1
9.	1	2	3	4
10.	4	3	2	1
11.	4	3	2	1
12.	1	2	3	4
13.	1	2	3	4
14.	1	2	3	4
15.	4	3	2	1
16.	4	3	2	1
17.	1	2	3	4
18.	1	2	3	4
19.	4	3	2	1
20.	4	3	2	1

Form Y-2

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21.	4	3	2	1
22.	1	2	3	4
23.	4	3	2	1
24.	1	2	3	4
25.	1	2	3	4
26.	4	3	2	1
27.	4	3	2	1
28.	1	2	3	4
29.	1	2	3	4
30.	4	3	2	1
31.	1	2	3	4
32.	1	2	3	4
33.	4	3	2	1
34.	4	3	2	1
35.	1	2	3	4
36.	4	3	2	1
37.	1	2	3	4
38.	1	2	3	4
39.	4	3	2	1
40.	1	2	3	4

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Gastroparesis Registry 2

UG – Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)

Purpose: To assess quality of life in patients with gastroparesis.
When: Screening visit s and follow-up visits f024, f048, f072, f096, f120, f144, f168, and f192.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed forms.
Respondent: Patient, without help from spouse or family.
Instructions: The Clinical Coordinator should complete section A and attach a label to each of pages 2-4.
Screening: The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-4. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to pages 2-4 and the Clinical Coordinator should complete section B.
Followup: Pages 2-4 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and to bring the completed form to the next study visit. When the patient returns for the visit, the Clinical Coordinator should review the form for completeness and obtain responses for missing items during the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be attached to pages 2-4 and the Clinical Coordinator should complete section B. Fill in item 4 with the date the patient wrote in item 40. If the patient did not write in a date, use the date of the study visit.

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: _____ _____ _____ _____

6. Form & revision: u g 1

7. Study: GpR 2 5

B. Administrative information

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

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

____

9. Date form reviewed:

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

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Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

PAGI - Qol

Instructions: The following questions ask about how some of the gastrointestinal problems you may be experiencing (such as pain, discomfort or other problems) may have affected your overall quality of life and well-being in the past 2 weeks.

Please answer every question by *circling the number* that best represents your opinion. There are no right or wrong answers.

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

During the past 2 weeks, because of your gastrointestinal problems, how often...	**None of the time**	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
10. have you had to depend on others to do your daily activities?	0	1	2	3	4	5
11. have you avoided performing your daily activities?	0	1	2	3	4	5
12. have you had difficulty concentrating?	0	1	2	3	4	5
13. has it taken you longer than usual to perform your daily activities?	0	1	2	3	4	5
14. have you felt tired?	0	1	2	3	4	5
15. have you lost the desire to participate in social activities such as visiting friends or relatives?	0	1	2	3	4	5
16. have you been worried about having stomach symptoms in public?	0	1	2	3	4	5
17. have you avoided performing physical activities or sports?	0	1	2	3	4	5
18. have you avoided traveling?	0	1	2	3	4	5

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

During the past 2 weeks, because of your gastrointestinal problems, how often...	**None of the time**	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
19. have you felt frustrated about not being able to do what you wanted to do?	0	1	2	3	4	5
20. have you felt constricted in the clothes you wear?	0	1	2	3	4	5
21. have you felt frustrated about not being able to dress as you wanted to?	0	1	2	3	4	5
22. have you felt concerned about what you can and cannot eat?	0	1	2	3	4	5
23. have you avoided certain types of foods?	0	1	2	3	4	5
24. have you restricted eating at restaurant or at someone's home?	0	1	2	3	4	5
25. have you felt less enjoyment in food than usual?	0	1	2	3	4	5
26. have you felt concerned that a change in your food habits could trigger your symptoms?	0	1	2	3	4	5
27. have you felt frustrated about not being able to choose the food you wanted to?	0	1	2	3	4	5
28. have you felt frustrated about not being able to choose the type of beverage you wanted to?	0	1	2	3	4	5
29. has your relationship with your spouse or partner been disturbed?	0	1	2	3	4	5

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Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

During the past 2 weeks, because of your gastrointestinal problems, how often...	**None of the time**	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
30. has your relationship with your children or relatives been disturbed?	0	1	2	3	4	5
31. has your relationship with your friends been disturbed?	0	1	2	3	4	5
32. have you been in a bad mood?	0	1	2	3	4	5
33. have you felt depressed?	0	1	2	3	4	5
34. have you felt anxious?	0	1	2	3	4	5
35. have you felt angry?	0	1	2	3	4	5
36. have you felt irritable?	0	1	2	3	4	5
37. have you felt discouraged?	0	1	2	3	4	5
38. have you been stressed?	0	1	2	3	4	5
39. have you felt helpless?	0	1	2	3	4	5

40. Date form completed: _____ _____-_____ _____ _____-_____ _____

day mon year

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