Gastroparesis Registry 2

AE - Adverse 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.

When: All visits. Use visit code if reporting an event discovered during a regular follow-up visit. Use visit code n if event is discovered between study visits. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code for first event, n for second event, n2 for third event, etc.

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 19) and the severity code (item 20) 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: Erin Hallinan) a copy of this form if severity grade is 3 or higher (Fax 443-287-5797).

GpCRC Data Coordinating Center telephone number: (443) 287-3170.

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: ____ ____ ____ ____

6. Form & revision: a e 1

7. Study: GpR 2 5

B. Visit interval identification

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

Yes (1) No (2)

25. ___

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

a. Date: ____ ____–____ ____ ____–____ ____
day mon year

b. Visit code: ____ ____ ____ ____

C. Patient information

10. Gender:

Male (1)

Female (2)

11. Age at time of event: ____ ____ years

D. Event description

12. Date event started:

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

13. 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)

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

g. Study procedure related event: (1)

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

_____

_____

_____

_____

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

a. Emergency Room visit: (1)

b. Hospitalization: (1)

c. Surgical intervention(s) *(specify):* (1)

_____

_____

d. Doctor visit *(specify):* (1)

_____

_____

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

_____

_____

16. Describe event:

_____

_____

_____

_____

_____

_____

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

Yes (1) No (2)

If yes, specify:

_____

_____

_____

_____

For items 18, 19, and 20, please refer to CTCAE v3.0 available at www.gpcrc.com; click on Studies and then GpR 2.

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

a. Auditory/ear: (1)

b. Allergy/immunologic: (1)

c. Ocular/visual: (1)

d. Hepatobiliary/pancreatic: (1)

e. Infection: (1)

f. Constitutional symptoms: (1)

g. Psychiatric: (1)

h. Cardiovascular: (1)

i. Dermatologic/skin: (1)

j. Endocrine/metabolic: (1)

k. Gastrointestinal/digestive: (1)

l. Lymphatic/blood: (1)

m. Musculoskeletal: (1)

n. Neurologic: (1)

o. Pulmonary/respiratory: (1)

p. Renal/genitourinary: (1)

q. Sexual/reproductive: (1)

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

_____

specify other body system

s. None of the above: (1)

19. Short name for event if applicable

Not applicable (0)

_____

_____

20. Severity grade

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.*

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

Resolved (1)

Active (2)

23. ___

Unknown (3)

23. ___

22. Date event resolved:

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

23. What action was taken:

24. Other comments on event:

E. Administrative information

25. Clinical Coordinator PIN: ____ ____ ____

26. Clinical Coordinator signature:

27. Study Physician PIN: ____ ____ ____

28. Study Physician signature:

29. Date form reviewed:

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

Key this form. If the severity grade is 3 or higher, fax the form to the DCC (Attention: Erin Hallinan) for review by Linda Lee, the Safety Officer.

Gastroparesis Registry 2

AE - Adverse 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.

When: All visits. Use visit code if reporting an event discovered during a regular follow-up visit. Use visit code n if event is discovered between study visits. If more than one event is reported on the same calendar day (ie, same date in item 4 for all events), use visit code for first event, n for second event, n2 for third event, etc.

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 19) and the severity code (item 20) are to be obtained from the NCI's Common Terminology Criteria for Adverse Events v4.03 (CTCAE). The CTCAE document is available at www.gpcrc.us; click on Documents. **Fax the DCC (Attention: Erin Hallinan) a copy of this form if severity grade is 3 or higher** (Fax 443-287-5797).

GpCRC Data Coordinating Center telephone number: (443) 287-3170.

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: ____ ____ ____ ____

6. Form & revision: a e 2

7. Study: GpR 2 5

B. Visit interval identification

8. Since the last visit, has the patient had a reportable event, not previously reported (if event was reported in interim using visit code "n", check No):

Yes (1) No (2)

25. ____

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

a. Date: ____ ____–____ ____ ____–____ ____
day mon year

b. Visit code: ____ ____ ____ ____

C. Patient information

10. Gender:

Male (1)
Female (2)

11. Age at time of event: ____ ____ years

D. Event description

12. Date event started: ____ ____–____ ____ ____–____ ____
day mon year

13. 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)

14. 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. Worsening of co-morbid illness: (1)
g. Study procedure related event: (1)
h. Other *(specify):* (1)

_____

_____

_____

_____

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

a. Emergency Room visit: (1)

b. Hospitalization: (1)

c. Surgical intervention(s) *(specify):* (1)

_____

_____

d. Doctor visit *(specify):* (1)

_____

_____

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

_____

_____

16. Describe event:

_____

_____

_____

_____

_____

_____

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

Yes (1) No (2)

If yes, specify:

_____

_____

_____

_____

For items 18, 19, and 20, please refer to CTCAE v4.03 available at www.gpcrc.com; click on Studies and then GpR 2.

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

a. Auditory/ear: (1)

b. Allergy/immunologic: (1)

c. Ocular/visual: (1)

d. Hepatobiliary/pancreatic: (1)

e. Infection: (1)

f. Constitutional symptoms: (1)

g. Psychiatric: (1)

h. Cardiovascular: (1)

i. Dermatologic/skin: (1)

j. Endocrine/metabolic: (1)

k. Gastrointestinal/digestive: (1)

l. Lymphatic/blood: (1)

m. Musculoskeletal: (1)

n. Neurologic: (1)

o. Pulmonary/respiratory: (1)

p. Renal/genitourinary: (1)

q. Sexual/reproductive: (1)

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

_____

specify other body system

s. None of the above: (1)

19. Indicate the short name for the event that you must obtain from the NCI's Common Terminology Criteria for Adverse Events v4.03 (CTCAE). The CTCAE document is available at www.gpcrc.us; click on Documents

_____

_____

a. Not in CTCAE (e.g., malignancy, data breach) *(specify):* (1)

_____

specify

20. Indicate the severity code using the CTCAE grading scale for the AE specified.

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

†*Fax the DCC (Attention Erin Hallinan) a copy of this form if severity grade is 3 or higher (Fax 443-287-5797).*

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

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

Resolved	(1)
Active	(2)
	23. ⌊
Unknown	(3)
	23. ⌊

22. Date event resolved:

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

23. What action was taken:

_____

_____

_____

_____

_____

_____

24. Other comments on event:

_____

_____

_____

_____

_____

_____

E. Administrative information

25. Clinical Coordinator PIN: ____ ____ ____

26. Clinical Coordinator signature:

_____

27. Study Physician PIN: ____ ____ ____

28. Study Physician signature:

_____

29. Date form reviewed:

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

Key this form. If the severity grade is 3 or higher, fax the form to the DCC (Attention: Erin Hallinan) for review by Linda Lee, the Safety Officer.

Gastroparesis Registry 2

AN - Autonomic Function Testing Results

Purpose: To record results reported by the ANX 3.0 System in order to detect dysfunction of the autonomic nervous system.

When: Screening visit and f048.

Instructions: Instruct patient to sit straight up with feet flat on the floor and arms resting comfortably at their sides. Patient should remain as still as possible and simply breathe freely at a comfortable pace unless instructed to do otherwise. No talking during the test. Use F10 key to record any events (cough, sneeze, talking, etc). There will be 6 Phases of the test (3 baselines, 2 breathing exercises, 1 stand challenge). Thirty seconds before the end of each phase, the time on the clock will switch to red. This is a reminder for you and the patient that the next challenge is about to begin. Have patient practice deep breathing and Valsalva challenges before the test begins.

1) Initial Baseline - 5 minutes of relaxed, normal, regular breathing. First blood pressure will be taken when the clock reads 2:00.

2) Deep Breathing - 1 minute of slow, easy, relaxed, deep breaths: 5 seconds in, 5 seconds out. NOTE: If patient is light-headed or dizzy, discontinue and use F10 to record event.

3) Baseline - 1 minute of relaxed, normal breathing.

4) Valsalva - Like you are trying to blow up a balloon that is difficult to blow up. Take a quick, deep breath in, hold the breath, and then bear down. Focus on bearing down in the chest and stomach and keep arms as relaxed as possible. Tell the patient that he/she will be performing 5 Valsalva maneuvers.

5) Baseline - 2 minutes of relaxed, normal breathing. Do NOT remind patient that stand phase is about to begin. Make certain that lead/blood pressure wires are not under patients feet.

6) Stand - At the sound of the tone, instruct patient to stand. Stand next to patient in the event they need help standing or become dizzy upon standing. Patient should remain still and breathe normally.

Please remember to print and save a copy of the report in the patients research file. For more information on administering the autonomic function test, please refer to the document ''How to administer a test'' on the GpCRC website by clicking on Studies > Gastroparesis Registry 2 Study > Autonomic Function Testing.

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: a n 1

7. Study: GpR 2 5

B. Initial Baseline (Resting) over 5 minutes

8. Date of test:

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

9. Mean Heart Rate: ____ ____ ____ bpm

a. Interpretation:

- Low (1)
- Normal (2)
- Elevated (3)
- High (4)
- Not applicable (5)
- Other *(specify)* (6)

_____
specify

10. Range Heart Rate (RangeHR): ____ ____ ____
bpm

a. Interpretation:

Low	(1)
Normal	(2)
High	(3)
Not applicable	(4)
Other *(specify)*	(5)

_____
specify

11. Sympathetic Modulation (LFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

12. Parasympathetic Modulation (RFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

13. Sympathovagal Balance (LFa/RFa):

____ ____ ____ • ____ ____

a. Interpretation:

Low	(1)
Low normal	(2)
Normal	(3)
High normal	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

14. Systolic blood pressure (SBP):

____ ____ ____
mmHg

a. Interpretation:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Not applicable	(5)
Other *(specify)*	(6)

_____
specify

15. Diastolic Blood Pressure (DBP):

____ ____ ____
mmHg

a. Interpretation:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Not applicable	(5)
Other *(specify)*	(6)

_____
specify

C. Deep Breathing for one minute

16. Parasympathetic Response (RFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

17. Range Heart Rate (RangeHR): ____ ____ ____
bpm

a. Interpretation:

Low	(1)
Normal	(2)
High	(3)
Not applicable	(4)
Other *(specify)*	(5)

_____
specify

18. Systolic blood pressure (SBP): ____ ____ ____
mmHg

a. SYS change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

19. Diastolic Blood Pressure (DBP):

____ ____ ____
mmHg

a. DIA change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

D. Valsalva

20. Sympathetic Response (LFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

21. Parasympathetic Response (RFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

22. Range Heart Rate (RangeHR): ____ ____ ____ bpm

a. Interpretation:

Low	(1)
Normal	(2)
High	(3)
Not applicable	(4)
Other *(specify)*	(5)

specify

23. Systolic blood pressure (SBP): ____ ____ ____ mmHg

a. SYS change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

specify

24. Diastolic Blood Pressure (DBP):

____ ____ ____ mmHg

a. DIA change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

specify

E. Standing over 5 minutes

25. Mean Heart Rate: ____ ____ ____ bpm

a. Interpretation:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Not applicable	(5)
Other *(specify)*	(6)

specify

26. Range Heart Rate (RangeHR; Max-Min):

____ ____ ____ bpm

a. Interpretation:

Low	(1)
Normal	(2)
High	(3)
Not applicable	(4)
Other *(specify)*	(5)

specify

27. Sympathetic Response (LFa):

____ ____ ____ • ____ ____ bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Borderline	(6)
Not applicable	(7)
Other *(specify)*	(8)

specify

28. Parasympathetic Response (RFa):

____ ____ ____ • ____ ____
bpm^2

a. Interpretation:

Low	(1)
Borderline low	(2)
Normal	(3)
Borderline high	(4)
High	(5)
Borderline	(6)
Not applicable	(7)
Other *(specify)*	(8)

_____
specify

29. Systolic blood pressure (SBP): ____ ____ ____
mmHg

a. SYS change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

30. Diastolic Blood Pressure (DBP):

____ ____ ____
mmHg

a. DIA change:

Low	(1)
Normal	(2)
Elevated	(3)
High	(4)
Borderline	(5)
Not applicable	(6)
Other *(specify)*	(7)

_____
specify

31. Were any ectopic beats present:

Yes (1) No (2)

32. Comments on the autonomic function testing:

_____

_____

_____

F. Administrative information

33. Date form reviewed:

____ ____ – ____ ____ – ____ ____
day mon year

34. Clinic coordinator ID: ____ ____ ____

35. Clinic coordinator signature:

_____

Gastroparesis Registry 2

AP – GpCRC Abdominal Pain Questionnaire

Purpose: To assess the severity and nature of abdominal pain in gastroparesis patients.
When: Screening visit s and follow-up visits f048, f096, f144, f192 and f240.
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 2-7. **Screening:** The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-7. 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 2-7 and the Clinical Coordinator should complete section B.
Follow-up: Pages 2-7 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 2-7 and the Clinical Coordinator should complete section B. Fill in item 4 with the date the patient wrote in item 36. 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: **a p 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

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

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

GpCRC Abdominal Pain Questionnaire

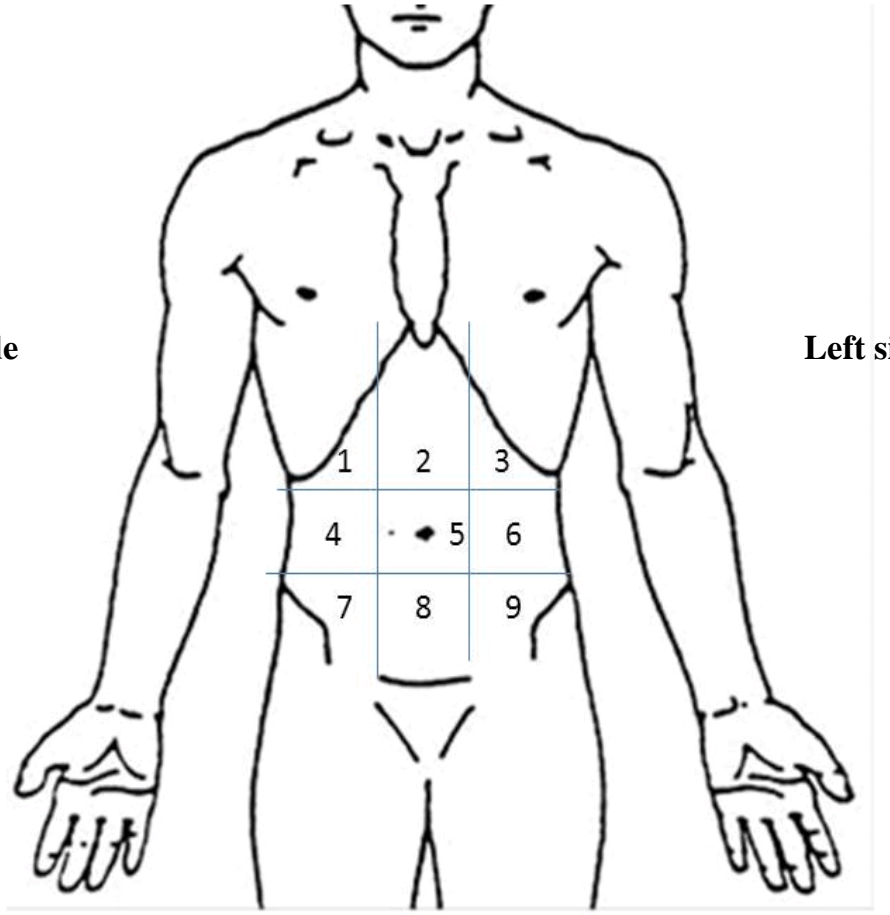
This questionnaire is to better understand abdominal pain in patients with gastroparesis. Some of these questions may seem repetitive; however these questions will help us better characterize your abdominal pain.

10. Do you experience abdominal pain?

Yes (1) No (2) → *If No, skip to question 36.*

a. On the diagram below, please place **one X** in the area where you feel the **most severe** abdominal pain. Please limit your answer to the location of your abdominal pain.

Right side **Left side**



Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

11. Please check the most appropriate word describing your <u>current</u> type of abdominal pain *(check only one)*:

No pain	(1)
Mild	(2)
Discomforting	(3)
Distressing	(4)
Horrible	(5)
Excruciating	(6)

12. How often do you experience abdominal pain *(check only one)*:

Less than 1 day a month	(1)
One day a month	(2)
Two to 3 days a month	(3)
One day a week	(4)
More than one day a week	(5)
Everyday	(6)

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

The words below describe abdominal pain. Circle the number that represents the degree to which <u>each</u> of the following descriptions below describes your abdominal pain with **"0"** being **"None" and "3" being "Severe".** Please limit your answers to a description of your **<u>abdominal pain</u>** *(circle only one)*:

		None	Mild	Moderate	Severe
13.	Throbbing	0	1	2	3
14.	Shooting	0	1	2	3
15.	Stabbing	0	1	2	3
16.	Sharp	0	1	2	3
17.	Cramping	0	1	2	3
18.	Gnawing	0	1	2	3
19.	Hot-Burning	0	1	2	3
20.	Aching	0	1	2	3
21.	Heavy	0	1	2	3
22.	Tender	0	1	2	3
23.	Splitting	0	1	2	3
24.	Tiring-Exhausting	0	1	2	3
25.	Sickening	0	1	2	3
26.	Fearful	0	1	2	3
27.	Punishing-Cruel	0	1	2	3

Affix label here

Patient ID: __ __ __ __

Patient code: __ __ __

Visit code: __ __ __ __

28. On a scale from **00** (no pain) to **10** (worse possible pain), how bad has your abdominal pain been, on average, over the last 2 week *(circle only one)*:

00 01 02 03 04 05 06 07 08 09 10

29. Circle the number of days that you get pain over a 2 week (14 day) period? For example, if you circle 04, it means that you get pain 4 days out of every 14 days. If you get pain every day, circle 14 *(circle only one)*:

00 01 02 03 04 05 06 07 08 09 10 11 12 13 14

30. Is your abdominal pain present all of the time and every day *(check only one)*:

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

31. Does your abdominal pain worsen with eating *(check only one)*:

Yes ($_1$) No ($_2$) Sometimes ($_3$)

32. Does your abdominal pain improve with eating *(check only one)*:

Yes ($_1$) No ($_2$) Sometimes ($_3$)

33. Do you have abdominal pain at night *(check only one)*:

Yes ($_1$) No ($_2$) Sometimes ($_3$)

34. Does your abdominal pain interfere with your sleep *(check only one)*:

Yes ($_1$) No ($_2$) Sometimes ($_3$)

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

35. Do you experience acute episodes of abdominal pain?

Yes (1) No (2) → *If No, skip to question 36.*

a. During a typical acute abdominal pain episode, how severe does your abdominal pain get on a scale from **00** (no pain) to **10** (worst imaginable pain) *(circle only one)*:

00 01 02 03 04 05 06 07 08 09 10

b. Circle the number of days you have acute episodes of abdominal pain over a typical 30-day period. For example, if you circle 04, it means that you have pain episodes 4 days out of every 30 days. If you have episodes every day, circle 30 *(circle only one)*:

00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

c. On a typical day when you do have acute abdominal pain episodes, how many episodes do you have during the day? For example, if you write 004, that means you experience 4 pain episodes during a typical day (even if your pain episodes varies from day to day, please give us your best estimate):

___ ___ ___

d. When you do have an acute abdominal pain episode, about how long does your episode typically last *(check only one)*:

Less than 1 minute	(1)
1 to 10 minutes	(2)
10 to 30 minutes	(3)
30 min to 1 hour	(4)
Over 1 hour to 4 hours	(5)
All day long	(6)
2 days	(7)
More than 2 days	(8)

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

e. When you have an acute abdominal pain episode, how quickly does the episode usually come on *(check only one)*:

Seconds to a minute	(1)
1 to 5 minutes	(2)
5 to 10 minutes	(3)
10 to 30 minutes	(4)
30 minutes to an hour	(5)
Over 1 to 2 hours	(6)
Several hours	(7)

f. Some people with gastroparesis can predict when a pain episode is about to come on while others cannot. In thinking about your abdominal pain episodes, how reliably can you predict, in advance that an episode is about to happen on a scale from **00** (totally unpredictable) to **10** (totally predictable) *(circle only one)*:

00 01 02 03 04 05 06 07 08 09 10

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

Gastroparesis Registry 2

BD - Beck Depression Inventory

Purpose: To collect data on the psychosocial aspects of gastroparesis in the Gastroparesis Registry 2 study.
When: Screening visit s and follow-up visits f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.
Administered by: Self-administered, but Clinical Coordinator must be available at visit to answer questions and to review completed questionnaire.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to each of pages 2-9. The patient should meet with the Clinical Coordinator, be trained in completion of the questionnaire, and then should complete pages 2-9. Page 1 should be reattached to pages 2-9 and the Clinical Coordinator should review the completed questionnaire for missing responses, complete sections B and C and resolve any problems before the patient leaves the clinical center.
Follow-up: At follow-up visits, special attention should be paid to statements 16 (changes in sleeping pattern) and 18 (changes in appetite) , where there are seven answer options (see SOP I, section 6.16). If the patient indicates a different answer for either of these as compared to when they last completed the form, the presence of an increase or decrease in either of these statements could be of clinical significance; please follow your clinical center's guidelines for patient care.
Scoring: If the patient has made more than one choice for an item, use the highest scoring item. In statements 16 and 18, where there are seven answer options (0, 1a, 1b, 2a, 2b, 3a, 3b), a and b options are given the same weight. Only items on page 1 are keyed to the database.

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: b d 1

7. Study: GpR 2 5

B. Scoring information

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

8. Sum of all 21 statements: ____ ____
(0-63)

9. Is the sum greater than 28: Yes (*1) No (2)

10. Did the patient respond with a 2 or a 3 in statement 2: Yes (*1) No (2)

11. Did the patient respond with a 2 or a 3 in statement 9: Yes (*1) No (2)

** If "Yes" is checked for items 9, or 10, or 11, this suggests that the patient may be severely depressed; please follow your clinical center's guidelines for patient care.*

C. Administrative information

12. Clinical Coordinator PIN: ____ ____ ____

13. Clinical Coordinator signature:

_____

14. Date form reviewed:

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

Keyed: ( )

Gastroparesis Registry 2

BH - Baseline Medical History

Purpose: To collect baseline history information about the patient to screen for potential enrollment into the Gastroparesis Registry 2.

When: Screening visit s.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.f

Instructions: Collect information by interview and/or chart review. Enter "**m**" if the patient does not know the answer to a query. If a C is checked for any item, further review is necessary by the study physician who will determine whether the diagnosis or condition in the C item renders the patient ineligible for or unlikely to comply with the requirements of the GpR 2 study. If a STOP or Elig is checked for any item, the patient is ineligible and cannot enroll in the Gastroparesis Registry 2 unless the item can be resolved within the 112 day screening window. The BH form cannot be keyed to the data system if there is a STOP or Elig item present. The form should be retained in a study file for further evaluation as appropriate.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

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

5. Visit code: s ____ ____ ____

6. Form & revision: b h 1

7. Study: GpR 2 5

B. Gastroparesis history

8. Has the patient had symptoms of gastroparesis of at least 12 weeks duration *(do not have to be contiguous)* with varying degrees of nausea, vomiting, abdominal pain, early satiety, or post-prandial fullness:

Yes (1) No (2)
STOP

These next 6 questions ask about the period in the past when your gastroparesis symptoms started

9. Date symptoms of gastroparesis or functional dyspepsia started:

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

10. Which best describes the onset of gastroparesis or functional dyspepsia symptoms *(check only one):*

Acute start (1)
Insidious or gradual (2)
Other *(specify)* (3)

_____
specify

11. Did the patient have an initial infectious prodrome with resultant chronic gastroparesis symptoms:

Yes (1) No (2)
13.

12. Specify infectious symptoms *(check only one):*

Upper respiratory flu-like illness *(fever, cough, body aches):* (1)

Food-poisoning like symptoms *(nausea, vomiting after eating bad food):* (2)

Gastroenteritis *(nausea, vomiting, diarrhea):* (3)

Other *(specify):* (4)

_____
specify

13. 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

14. Select the **<u>one predominant symptom</u>** listed in item 13 (a through n) that prompted the evaluation for gastroparesis: ____
a-n

These next 3 questions ask about your current symptoms of gastroparesis.

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

Chronic symptoms, but stable severity of symptoms (1)
Chronic symptoms, but progressive worsening of symptoms (2)
Chronic symptoms, but with some improvement over time (3)
Chronic symptoms with periodic exacerbations with worsening of symptoms (4)
Cyclic pattern of exacerbations with periods of feeling well in between (5)
Asymptomatic (6)
Other *(specify):* (7)

_____
specify

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

(Grade 1) Mild gastroparesis: *Symptoms mild to moderate and relatively 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, ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via oral route.* (3)
Other *(specify):* (4)

_____
specify

17. What is the investigator's assessment of the patient's current symptoms of gastroparesis:

None	(0)
Very mild	(1)
Mild	(2)
Moderate	(3)
Severe	(4)
Very severe	(5)

18. What is the present understanding of the primary etiology of the patient's gastroparesis

a. Diabetes:	(1)
b. Post-Nissen fundoplication:	(1)
c. Idiopathic:	(1)
d. Other *(specify):*	(1)

Elig

_____
specify

C. Family history

19. Have members of the patient's family been diagnosed with gastroparesis:

Yes (1) No (2)

21.

20. Which family members *(check all that apply)*

a. Brother:	(1)
b. Sister:	(1)
c. Mother:	(1)
d. Father:	(1)
e. Son:	(1)
f. Daughter:	(1)
g. Spouse/partner:	(1)
h. Other *(specify)*	(1)

_____
specify

D. Weight history

21. What is the patient's current weight *(patient's report):*

___ ___ ___
lbs

22. What was the patient's approximate weight when diagnosed with gastroparesis or functional dyspepsia *(date in item 9):*

___ ___ ___
lbs

23. How does the patient's current weight compare to prior to the start of his/her gastroparesis or functional dyspepsia symptoms:

Increased	(1) → 24a.
Decreased	(2) → 24b.
Same	(3) → 25.

24. Weight compared to start of gastroparesis

a. How much more does the patient weigh now compared to the start of his/her gastroparesis:

___ ___ ___
lbs

25.

b. How much less does the patient weigh now compared to the start of his/her gastroparesis:

___ ___ ___
lbs

25. Weight prior to gastroparesis

a. What is the most the participant has ever weighed prior to the gastroparesis diagnosis:

___ ___ ___
lbs

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

___ ___
age in years

26. What is the least the patient has ever weighed since age 18, but prior to the start of gastroparesis or functional dyspepsia symptoms:

___ ___ ___
lbs

27. At what age did the patient weigh the least since age 18, but prior to the gastroparesis symptoms:

___ ___
age in years

28. Over the last six months, has the patient gained weight, lost weight, or stayed the same:

- Gained weight (1)
- Lost weight (2)
- Stayed the same (3)

29. What was the patient's approximate weight six months ago:

____ ____ ____
lbs

30. *Review flashcard #7* Which (picture) best describes your weight pattern over the past 5 years *(check only one):*

- Up and down, up and down (1)
- Up gradually (2)
- Up sharply (gained a lot in a brief interval) (3)
- Down gradually (4)
- Down sharply (lost a lot in a brief interval) (5)
- No or minimal change (6)

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

31. Have you ever smoked tobacco cigarettes:

- No, never (1) → **36.**
- Yes, in the past but not anymore (2)
- Yes, currently smoke cigarettes (3)

32. 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) → **36.**

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

____ ____
years

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

____ ____
years

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

____ ____ ____
cigarettes/day

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

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

- Never (0) → **39.**
- 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)

37. How many drinks containing alcohol do you have 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)

38. How often have you had six or more alcoholic drinks on one occasion in the past year *(check only one):*

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

G. Menstrual history

39. Is the patient female:

Yes (1) No (2) → **43.**

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

- Regular periods (1) → **43.**
- Irregular periods (2)
- Rare periods (3)
- No periods (4)

41. Is patient postmenopausal *(natural or surgical):*

Yes (1) No (2)

→ **43.**

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

____ ____
age in years

H. Medical history

(C means CAUTION; Flags conditions that are exclusionary; verify with Study Physician)

43. Has the patient ever been diagnosed with diabetes *(NOT including gestational diabetes):*

Yes (1) No (2)

→ **50.**

44. Diabetes type:

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

45. Age when diagnosed: ____ ____
age in years

46. Weight when diagnosed: ____ ____ ____
lbs

47. Has the patient been diagnosed with any complications of diabetes:

Yes (1) No (2)

→ **50.**

If yes, check all that apply:

a. Retinopathy (eye changes from diabetes): (1)

b. Nephropathy (kidney disease from diabetes): (1)

c. Peripheral neuropathy (numbness and/or tingling in distal legs from diabetes): (1)

48. Has the patient had laser treatment for diabetic retinopathy:

Yes (1) No (2)

49. Has the patient had prior episodes of diabetic ketoacidosis (ketones present in the blood requiring hospitalization):

Yes (1) No (2)

50. 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 (IBD): (1) C

e. Irritable bowel syndrome (IBS): (1)

f. Eosinophilic gastroenteritis: (1) C

g. Acute renal failure: (1) C

h. Acute liver failure: (1) C

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

j. Hepatitis B: (1)

k. Hepatitis C: (1)

l. Peptic ulcer disease: (1)

m. GERD: Gastroesophageal reflux disease: (1)

n. Celiac disease: (1)

o. Small intestinal bacterial overgrowth (SIBO): (1)

p. Colonic inertia: (1)

q. Interstitial cystitis: (1)

r. Bladder dysfunction: (1)

s. Diverticulosis: (1)

t. Endometriosis: (1)

u. Blood clots: (1)

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

w. Rheumatoid arthritis: (1)

x. Scleroderma: (1)

y. Systemic lupus erythematosus: (1)

z. Collagen vascular disease: (1)

aa. Raynaud's phenomenon: (1)

ab. Other unidentified systemic autoimmune disorder: (1)

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

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

ae. Peripheral neuropathy *(non-diabetic numbness or tingling in hands or legs):* (1)

af. Migraine headaches: (1)

ag. Chronic headaches ≥ 15 per month (other than migraines): (1)

ah. Seizure disorder or epilepsy: (1)

ai. Chronic fatigue syndrome: (1)

aj. Hypertension: (1)

ak. Heart attack, myocardial infarction: (1)

al. Coronary artery disease: (1)

am. Cerebrovascular disease: (1)

an. Stroke, cerebrovascular accident (CVA): (1)

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

ap. Pancreatitis: (1)

aq. Cholelithiasis: (1)

ar. Gallbladder disease without gallstones including chronic cholecystitis, gallbladder dyskinesia: (1)

as. Gout: (1)

at. Polycystic ovary syndrome (PCOS): (1)

au. Dermatologic disorders: (1)

av. Myopathy: (1)

aw. Fibromyalgia: (1)

ax. Multiple sclerosis: (1)

ay. Parkinson's disease: (1)

az. ALS: Amyotrophic lateral sclerosis: (1)

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

bb. Major depression requiring treatment: (1)

bc. Schizophrenia: (1)

bd. Bipolar disorder: (1)

be. Obsessive compulsive disorder: (1)

bf. Severe anxiety disorder requiring treatment: (1)

bg. Personality disorder requiring treatment: (1)

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

bi. Primary neurologic conditions that could cause nausea and/or vomiting such as increased intracranial pressure, space occupying or inflammatory/infectious lesions: (1)

bj. Chronic renal failure and/or hemodialysis or peritoneal dialysis: (1)

bk. None of the above: (1)

51. Has the patient ever had any abdominal and/or pelvic surgical procedures:

Yes (1) No (2)

52. Has the patient ever had a total gastric resection:

Yes (1) No (2)

53. Has the patient ever had a gastrojejunostomy, esophagogastrostomy or gastric bypass:

Yes (1) No (2)

54. Has the patient ever had a subtotal gastric resection (vagotomy, pyloroplasty, antrectomy):

Yes (1) No (2)

(1) → Elig

55. Has the patient ever had stapling or banding of the stomach:

Yes (1) No (2)

(1) → Elig

56. Has the patient ever had a Nissen fundoplication for GERD:

Yes (1) No (2) → 57.

a. Date:

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

b. Did current gastroparesis symptoms start before or after Nissen fundoplication for GERD:

Before (1)
After (2)

57. Has the patient ever had a cholecystectomy (gallbladder removal):

Yes (1) No (2) → 58.

a. Date:

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

b. Were there gallstones in the gallbladder:

Yes (1) No (2)

c. Did the patient's symptoms that led to the gallbladder removal improve after removal of the gallbladder:

Yes (1) No (2)

d. Did current gastroparesis symptoms start before or after the removal of the gallbladder:

Before (1)
After (2)

58. Has the patient had an appendectomy:

Yes (1) No (2) → 59.

a. Date:

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

b. Did current gastroparesis symptoms start before or after the appendectomy:

Before (1)
After (2)

59. Has the patient had a hysterectomy:

Yes (1) No (2) → 60.

a. Date:

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

b. Did current gastroparesis symptoms start before or after the hysterectomy:

Before (1)
After (2)

60. Has the patient had a Caesarean section:

Yes (1) No (2) → 61.

a. Date:

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

b. Did current gastroparesis symptoms start before or after the C-section:

Before (1)
After (2)

61. Has the patient been hospitalized for gastroparesis symptoms in the past year:

Yes (1) No (2) → 64.

62. How many times was the patient hospitalized for gastroparesis in the past year:

____ ____ ____

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

a. Nausea: (1)
b. Vomiting: (1)
c. Abdominal pain: (1)
d. Dehydration: (1)
e. Hyperglycemia: (1)
f. Hypoglycemia: (1)
g. GI bleed: (1)
h. Other *(specify):* (1)

_____
specify

I. Nutrition and Gastric Electrical Stimulator (GES) use

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

Yes (1) No (2)

65. On most days during the last 6 months, did the patient follow a gastroparesis diet: small, more frequent meals, low fat, low fiber meals:

Yes (1) No (2)

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

Yes (1) No (2)

67. 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)

68. Does the patient have a G tube:

Yes (1) No (2) → **70.**

a. G tube has been in place since:

____ ____ ____–____ ____
month year

69. 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

70. Does the patient have a J tube:

Yes (1) No (2) → **72.**

a. J tube has been in place since:

____ ____ ____–____ ____
month year

71. 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

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

Yes (1) No (2)

74.

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

____ ____ ____–____ ____
month year

73. 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

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

Yes (1) No (2)

75.

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

____ ____ ____–____ ____
month year

b. In the patient's opinion, has the gastric electrical stimulator (GES) improved his/her gastroparesis symptoms:

Yes (1) No (2)

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

Yes (1) No (2)

75.

d. Specify reason why it is turned off:

_____
specify

J. Medication use

75. Has the patient used insulin for diabetes in the past 6 months:

Yes (1) No (2)

76.

a. Has the patient used an insulin pump in the past 6 months:

Yes (1) No (2)

b. Is the patient currently using an insulin pump:

Yes (1) No (2)

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

Yes (1) No (2)

77.

(If yes, check all that apply):

a. Acarbose (Precose): (1)

b. Acetohexamide (Dymelor): (1)

c. Chlorpropamide (Diabinese): (1)

d. Exenetide (Byetta, Bydureon): (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. Pramlintide (Symlin): (1)

m. Repaglinide (Prandin): (1)

n. Rosiglitazone (Avandia): (1)

o. Sitagliptin (Januvia): (1)

p. Tolazamide (Tolinase): (1)

q. Tolbutamide (Orinase): (1)

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

_____
specify

77. Has the patient taken any anti-hyperlipidemic medications in the past 6 months:

Yes (1) No (2)

78.

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

a. HMG-COA reductase inhibitors (Atorvastatin [Lipitor], Simvastatin [Zocor], Rosuvastatin [Crestor], Fluvastatin sodium [Lescol], Lovastatin [Mevacor], Pravastatin sodium [Pravachol]):, (1)

b. Bile acid sequestrant (Colestipol hydrochloride [Colestid]: (1)

c. Fibric acid (Gemfibrozil [Lopid], Fenofibrate [Tricor]): (1)

d. Nicotinic acid (Niaspan): (1)

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

_____
specify

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

Yes (1) No (2)

79.

(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

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

Yes (1) No (2)

80.

(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

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

( ) Yes (1) ( ) No (2) → **81.**

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

a. Class III antiarrhythmic agent (Amiodarone [Pacerone]): ( ) (1)

b. Dihydropyridine calcium channel blocker (Amlodipine besylate [Norvasc], Felodipine [Plendil], Nifedipine [Adalat, Procardia]): ( ) (1)

c. Beta1-adrenergic blocker (Atenolol [Tenormin], Metoprolol [Lopressor]: ( ) (1)

d. Non-selective beta blocker (Carvedilol [Coreg], Propranolol [Inderal], Timolol maleate [Blocadren]): ( ) (1)

e. Angiotensin-converting-enzyme inhibitors (Benazepril [Lotensin], Captopril [Capoten], Enalapril [Vasotec], Lisinopril [Prinivil, Zestril], Ramipril [Altace], Quinapril [Accupril]): ( ) (1)

f. Alpha-2 adrenergic agonist (Clonidine [Catapres]): ( ) (1)

g. Digoxin (Lanoxin): ( ) (1)

h. Diltiazem (Cardizem): ( ) (1)

i. Alpha-1 adrenergic blocker (Doxazosin [Cardura], Terazosin [Hytrin]): ( ) (1)

j. Furosemide (Lasix): ( ) (1)

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

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

m. Angiotensin II receptor antagonist (Losartan potassium [Cozaar], Valsartan [Diovan], Candesartan [Atacand]): ( ) (1)

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

o. Verapamil (Calan): ( ) (1)

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

_____
specify

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

_____
specify

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

( ) Yes (1) ( ) No (2) → **82.**

(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. Androgens (Fluoxymesterone [Android-F, Halotestin], Methyltestosterone [Android], Nandrolone [Deca-Durabolin, Hybolin Decanoate, Kabolin]): ( ) (1)

g. Progestins (Norethindrone [Micronor], Progesterone [Prometrium], Norgestrel [Ovrette], Levonorgestrel [Norplant], Medroxyprogesterone [Cycrin, Provera], Megestrol [Megace]): ( ) (1)

h. Combination 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)

i. Synthetic anabolic steroids (Oxandrolone [Oxandrin], Oxymetholone [Anadrol]): ( ) (1)

j. Selective estrogen receptor modulator (Raloxifene [Evista], Tamoxifen [Nolvadex]): (1)

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

_____
specify

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

_____
specify

K. Medication use for gastroparesis symptoms

For items 82-91: Have the patient use flashcard #8 to indicate the duration of use and perceived benefit for gastroparesis symptoms for each medication he/she uses/used

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

Yes (1) No (2)

83.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Esomeprazole (Nexium):	____	____
b. Omeprazole (Prilosec, Zegerid):	____	____
c. Lansoprazole (Prevacid):	____	____
d. Pantoprazole (Protonix):	____	____
e. Rabeprazole (Aciphex):	____	____
f. Dexlansoprazole (Dexilant):	____	____
g. Ranitidine (Zantac):	____	____
h. Famotidine (Pepcid):	____	____
i. Nizatidine (Axid):	____	____
j. Cimetidine (Tagamet):	____	____
k. Antacids, *(specify):*	____	____

_____
specify

l. Other *(specify):*	____	____

_____
specify

m. Other *(specify):*	____	____

_____
specify

83. Is the patient currently taking any prokinetic medications :

Yes (1) No (2)

84.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Azithromycin (Zithromax):	____	____
b. Bethanechol (Duvoid, Urecholine):	____	____
c. Clarithromycin (Biaxin):	____	____
d. Domperidone (Motilium):	____	____
e. Erythromycin:	____	____
f. Metoclopramide (Reglan):	____	____
g. Other *(specify):*	____	____

_____
specify

h. Other *(specify):*	____	____

_____
specify

84. Has the patient ever had Botox injected into pylorus for his/her gastroparesis symptoms:

Yes (1) No (2)

86.

a. Perceived benefit: ____ 0-5

85. Has the patient had botulinum toxin (Botox) injected into pylorus for his/her gastroparesis symptoms in the last 4 weeks:

Yes (1) No (2)

86.

a. Perceived benefit: ____ 0-5

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

( ) Yes (1) ( ) No (2) → **87.**

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Prochlorperazine (Compazine):	____	____
b. Promethazine (Pentazine, Phenergan):	____	____
c. Trimethobenzamide (Benzacot, Stemetic, Tigan):	____	____
d. Meclizine (Antivert):	____	____
e. Serotonin (5-HT3) antagonists (Ondansetron [Zofran], Tropisetron [Navoban], Granisetron [Kytril Sancuso Patch], Palonosetron [Aloxi], Dolasetron [Anzemet]):	____	____
f. Neurokinin-1 receptor antagonists (Aprepitant [Emend]):	____	____
g. Tricyclic antidepressants (Amitriptyline [Elavil], Desipramine [Norpramin], Nortriptyline [Aventyl, Pamelor]):	____	____
h. Dronabinol (Marinol):	____	____
i. Tetracylcic antidepressants (Mirtazapine [Remeron]):	____	____
j. Bupropion (Wellbutrin):	____	____
k. Selective Serotonin Reuptake Inhibitors (SSRI)[Citalopram (Celexa), Escitalopram (Lexapro), Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft)]:	____	____
l. Venlafaxine (Effexor):	____	____
m. Anxiolytic (Buspirone [BuSpar]):	____	____
n. Chlordiazepoxide (Librax):	____	____
o. Benzodiazepines (Lorazepam [Ativan], Alprazolam [Xanax], Diazepam [Valium], Oxazepam [Serax], Clonazepam [Klonopin], Temazepam [Restoril, Temaz], Flurazepam):	____	____
p. Meprobamate (Equanil, Meprospan):	____	____
q. Quetiapine fumarate (Seroquel):	____	____
r. Other *(specify):*	____	____
_____ specify		
s. Other *(specify):*	____	____
_____ specify		

87. Is the patient currently using any of the following medications for constipation:

( ) Yes (1) ( ) No (2) → **88.**

(If yes, answer all that apply using flashcard #8):

	Benefit (0-5)
a. Polyethylene glycol (Miralax):	____
b. Lubiprostone (Amitiza):	____
c. Lactulose:	____
d. Bisacodyl (Dulcolax):	____
e. Methylnaltrexone (Relistor):	____
f. Colchicine (Colcrys):	____
g. Misoprostol (Cytotec):	____
h. Other *(specify):*	____
_____ specify	

88. Is the patient currently taking any pain relieving, analgesics, non-steroidal anti-inflammatory, or aspirin containing medications (non-narcotic) either regular usage or as needed basis (prn):

Yes (1) No (2)

89.

(If yes, answer all that apply using flashcard #8):

	Benefit (0-5)
a. Acetaminophen (Tylenol):	____
b. Aspirin - 325 mg:	____
c. Celecoxib (Celebrex):	____
d. Ibuprofen (Advil, Motrin):	____
e. Indomethacin (Indocin):	____
f. Naproxen (Aleve, Naprosyn):	____
g. Item no longer used:	____
h. Other *(specify):*	____

_____
specify

i. Other *(specify):*	____

_____
specify

j. Other *(specify):*	____

_____
specify

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

Yes (1) No (2)

91.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Acetaminophen (30 mg)/ codeine phosphate (Tylenol #3):	____	____
b. Acetaminophen (60 mg)/ codeine phosphate (Tylenol #4):	____	____
c. Acetaminophen/hydrocodone bitartrate (Lortab, Norco, Vicodin):	____	____
d. Acetaminophen/oxycodone hydrochloride (Percocet, Tylox):	____	____
e. Aspirin/oxycodone hydrochloride (Percodan):	____	____
f. Butalbital/acetaminophen/ caffeine (Esgic - Plus):	____	____
g. Fentanyl transdermal (Duragesic patch):	____	____
h. Fentanyl oral (Fentora, Actiq):	____	____
i. Hydromorphone hydrochloride (Dilaudid):	____	____
j. Oxycodone hydrochloride (OxyContin):	____	____
k. Methadone hydrochloride:	____	____
l. Morphine sulfate:	____	____
m. Pentazocine (Talacen):	____	____
n. Tapentadol (Nycynta):	____	____
o. Tramadol hydrochloride/acetaminophen (Ultram, Ultracet):	____	____
p. Other *(specify):*	____	____

_____
specify

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

a. Pain related to his/her gastroparesis symptoms: (1)

b. Headache pain: (1)

c. Leg pain: (1)

d. Back pain: (1)

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

_____
specify

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

Yes (1) No (2)

92.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Duloxetine (Cymbalta):	____	____
b. Gabapentin (Neurontin):	____	____
c. Pregabalin (Lyrica):	____	____
d. Other *(specify):*	____	____

_____
specify

L. Alternative therapies for gastroparesis symptoms

For items 92-93: Have the patient use flashcard #8 to indicate the duration of use and perceived benefit for each alternative therapy they have used for gastroparesis symptoms.

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

Yes (1) No (2)

93.

	Duration (1-5)	Benefit (0-5)
a. Probiotics:	____	____

_____
specify

_____
specify

b. Herbal supplements:	____	____

_____
specify

_____
specify

_____
specify

c. Acupuncture:	____	____
d. Acupressure bands/bracelets *(ie, Relief band):*	____	____
e. Reflexology:	____	____
f. Hypnotherapy:	____	____
g. Therapeutic Massage:	____	____
h. Other *(specify):*	____	____

_____
specify

93. Does the patient use marijuana:

Yes (1) No (2)

94.

(If yes, use flashcard #8 to answer items 93 a and b):

a. Duration of use *(1-5):* ____

b. Perceived benefit *(0-5):* ____

c. How often do you use marijuana:

Rarely (less than once per month)	(1)
About once per month	(2)
Several times a month	(3)
Several times a week	(4)
About once per week	(5)
Several times per week	(6)
About once per day	(7)
More than once per day	(8)

M. Administrative information

94. Study Physician PIN: ____ ____ ____

95. Study Physician signature:

_____

96. Clinical Coordinator PIN: ____ ____ ____

97. Clinical Coordinator signature:

_____

98. Date form reviewed:

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

Flash Card #8	Which BEST DESCRIBES the DURATION of use for the medication you took or are taking?
1	**Less than 1 month**
2	**1-6 months**
3	**6-11 months**
4	**1-2 years**
5	**More than 2 years**

Flash Card #8	Which BEST DESCRIBES the BENEFIT you received from the medication you took or are taking for your gastroparesis symptoms?
0	**Not taking for gastroparesis symptoms**
1	**No or minimal benefit for gastroparesis symptoms**
2	**Better**
3	**Much better**
4	**Worse**
5	**Much worse**

CG - Genetic Consent and Blood Collection Documentation

Gastroparesis Registry 2

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

When: Visit s or as needed during follow-up (during follow-up, use the visit code of the follow-up visit that is open).

By whom: Study Physician, Clinical Coordinator and laboratory personnel responsible for collection of blood.

Instructions: Complete this form based on the consent documents signed by the patient. If the patient changes his/her mind regarding consent for use of samples after the initial form is completed, complete a new CG form. If the patient consents, (1) Fill two 10 mL EDTA vacutainer tubes with blood, and (2) Pack the EDTA tubes in the specimen shippers supplied by the NIDDK Genetics Repository, and (3) Ship blood at ambient room temperature to the NIDDK Genetics Repository at Rutgers University on the same day blood is collected.

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed:

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: c g 1

7. Study: GpR 2 5

B. Consent for collection, storage, and use of blood samples for current and future genetic research

8. Previous to screening for GpR2, did this participant have a DNA sample banked at the Genetics Repository under another GpCRC study *(i.e., the initial Registry or NORIG)*:

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

10. ____

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

a. Registry ( ) (1)

b. NORIG ( ) (1)

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

_____
specify

20. ____

10. Does the patient consent to genetic research on gastroparesis that is currently planned by the GpR 2 study investigators:

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

11. Does the patient consent to future genetic research on gastroparesis by this study or other study investigators:

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

12. Does the patient consent to future genetic research not related to gastroparesis by this study or other study investigators:

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

13. Other information related to consent for genetic research that clinic staff feel needs to be keyed to the study database *(e.g., if your genetic consent had other options that are not covered by the 3 categories of use of samples specified above):*

_____
_____
_____
_____
_____

14. In your judgment, has the patient consented to collection of blood for DNA banking *(this question is asked in recognition that not all IRBs will have approved consent statements that include language that can be mapped into the questions in items 10 through 12; a response of "No" to this question (item 14) means that blood should NOT be collected for sending to the NIDDK Genetics Repository and if already collected, should be destroyed by the Genetics Repository):*

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

20. ____

C. Specimen for Genetics Repository

Attach MACO ID labels to two 10 mL EDTA tubes and fill each with blood; invert each tube gently 6 times to mix blood with additives; keep tubes at room temperature in the shipper provided until shipping to the NIDDK Genetics Repository the same day.

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

Yes (1)

16.

No, *(specify reason):* (2)

_____
specify

20.

16. Date and time of blood draw

a. Date:

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

b. Time:

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

17. Number of 10 mL EDTA tubes: ____

18. Form copy of tube labels:

GpR 2 Form CG
Pt: ccc- 9999, xyz
Gender
Age, yrs.: XX

19. Phlebotomist:

_____
print name

D. Administrative information

20. Study Physician PIN: ____ ____ ____

21. Study Physician signature:

_____

22. Clinical Coordinator PIN: ____ ____ ____

23. Clinical Coordinator signature:

_____

24. Date form reviewed:

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

Gastroparesis Registry 2

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 s:** The screening upper gastrointestinal endoscopy procedure must have been performed within 24 months prior to registration. **Follow-up visits:** The form should be completed at visits f048, f096, f144, f192 and f240. 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.

Screening 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 EHG 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 EHG 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 1

7. Study: GpR 2 5

B. Upper endoscopy

8. Are upper endoscopy results available at this visit:

Yes (* 1) → **8b.** No (2) → **8a.**

** Results required at screening visit s.*

a. Is this screening visit s:

Yes (* 1) → **21.** No (2) → **23.**

b. Date of upper endoscopy:

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

** (Date of upper endoscopy must be within 24 months prior to the registration date at screening visit s)*

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) No (2)

11.

(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) No (2)
→ 13.

(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. Nissen fundoplication: (1)
g. Other fundoplication: (1) → C
h. Other subtotal resection *(vagotomy):* (1) → Elig
i. Stapling or banding of the stomach: (1) → Elig
j. Other gastric surgery *(specify):* (1) → C

_____
other specify

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

(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) No (2)
→ 16.

(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) No (2) → 18.

(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) No (2) → 20.

(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 s: Yes (1) No (2) → 23.

a. Is date in item 8b. within 24 months prior to registration date: Yes (1) No (2) → STOP

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

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

Gastroparesis Registry 2

FH - Follow-up Medical History

Purpose: To collect follow-up medical information about the patient.
When: f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.
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 1

7. Study: GpR 2 5

B. Interval identification

8. Date of last Follow-up Medical History form *(if this is f024, record date of Baseline History form):*

____ ____–____ ____ ____–____ ____
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. No symptoms related to gastroparesis: (1)

13. ____

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

13. Since the date in item 8, has the patient experienced any exacerbation(s) of his/her gastroparesis symptoms:

(Yes 1) (No 2)

17. ____

a. Number of Emergency room visits due to gastroparesis symptoms:

____ ____

14. Since the date in item 8, has the patient been admitted to the hospital for gastroparesis:

(Yes 1) (No 2)

17. ___

15. Since the date in item 8, how many times has the patient been admitted to the hospital for gastroparesis: ___ ___

16. 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

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

Chronic symptoms, but stable severity of symptoms (1)

Chronic symptoms, but progressive worsening of symptoms (2)

Chronic symptoms, but with some improvement over time (3)

Chronic symptoms with periodic exacerbations with worsening of symptoms (4)

Cyclic pattern of exacerbations with periods of feeling well in between (5)

Asymptomatic (6)

Other *(specify):* (7)

_____
specify

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

(Grade 1) Mild gastroparesis: *Symptoms mild to moderate and relatively 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)*

19. 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)

22. ___

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

___
days

21. 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)*

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

Never (0)

25. ___

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)

23. Since the date in item 8, how many drinks of alcohol, beer, or wine 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)

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

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

F. Menstrual history

25. Is the patient female: Yes (1) No (2)

31. ___

26. 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)

31. ___

27. Has the patient been pregnant since the date in item 8: Yes (1) No (2)

28. ___

a. If yes, what is the status of the pregnancy:

Still pregnant	(1)
Delivery of child	(2)
Miscarriage	(3)
Abortion	(4)

28. Since the date in item 8, did the patient have a hysterectomy: Yes (1) No (2)

29. Is the patient postmenopausal *(surgical or natural):* Yes (1) No (2)

31. ___

30. Since the date in item 8, has the patient entered natural menopause: Yes (1) No (2)

G. Medical history

31. Is the patient diabetic: Yes (1) No (2) → **34.**

a. Is this diagnosis of diabetes new since the date in item 8: Yes (1) No (2)

32. 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 *(symptomatic and/or requiring intervention)* (1)

c. Glucose levels above 300 mg/dL: (1)

d. Episodes of diabetic ketoacidosis: (1)

e. Postprandial high glucose levels (1)

f. Postprandial low glucose levels (1)

33. Since the date in item 8, has the patient been diagnosed with or treated for any of the following complications of diabetes: Yes (1) No (2) → **34.**

If yes, check all that apply:

a. Retinopathy (eye changes from diabetes): (1)

b. Nephropathy (kidney disease from diabetes): (1)

c. Peripheral neuropathy (numbess and/or tingling in distal legs from diabetes): (1)

34. Since the date in item 8, 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. Intestinal obstruction: (1)

d. Inflammatory bowel disease (IBD): (1)

e. Irritable bowel syndrom (IBS): (1)

f. Eosinophilic gastroenteritis: (1)

g. Acute renal failure: (1)

h. Acute liver failure: (1)

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

j. Hepatitis B: (1)

k. Hepatitis C: (1)

l. Peptic ulcer disease: (1)

m. GERD: Gastroesophageal reflux disease: (1)

n. Celiac disease: (1)

o. Small intestinal bacterial overgrowth (SIBO): (1)

p. Colonic inertia: (1)

q. Interstitial cystitis: (1)

r. Bladder dysfunction: (1)

s. Diverticulosis: (1)

t. Endometriosis: (1)

u. Blood clots: (1)

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

w. Rheumatoid arthritis: (1)

x. Scleroderma: (1)

y. Systemic lupus erythematosus: (1)

z. Collagen vascular disease: (1)

aa. Raynaud's phenomenon: (1)

ab. Other unidentified systemic autoimmune disorder: (1)

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

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

ae. Peripheral neuropathy (non-diabetic numbess or tingling in hands or legs): (1)

af. Migraine headaches: (1)

ag. Chronic headaches ≥ 15 per month (other than migraines): (1)

ah. Seizure disorder or epilepsy: (1)

ai. Chronic fatigue syndrome: (1)

aj. Hypertension: (1)

ak. Heart attack, myocardial infarction: (1)

al. Coronary artery disease: (1)

am. Cerebrovascular disease: (1)

an. Stroke, cerebrovascular accident (CVA): (1)

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

ap. Pancreatitis: (1)

aq. Cholelithiasis: (1)

ar. Gallbladder disease without gallstones including chronic cholecystitis, gallbladder dyskinesia: (1)

as. Gout: (1)

at. Polycystic ovary syndrome (PCOS): (1)

au. Dermatologic disorders: (1)

av. Myopathy: (1)

aw. Fibromyalgia: (1)

ax. Multiple sclerosis: (1)

ay. Parkinson's disease: (1)

az. ALS: Amyotrophic lateral sclerosis: (1)

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

bb. Major depression: (1)

bc. Schizophrenia: (1)

bd. Bipolar disorder: (1)

be. Obsessive compulsive disorder: (1)

bf. Severe anxiety disorder: (1)

bg. Personality disorder: (1)

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

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

_____
specify

bj. None of the above: (1)

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

Yes (1) No (2)

36. ___

(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. Gastrojejunostomy: (1)

e. Fundoplication for GERD: (1)

f. Nissen fundoplication for GERD: (1)

g. Cholecystectomy *(gall bladder removal):* (1)

h. Gastrostomy *(surgical or endoscopic):* (1)

i. Jejunostomy: (1)

j. Appendectomy: (1)

k. Hysterectomy: (1)

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

_____
specify

H. Nutrition and gastric electrical stimulator (GES) use

36. 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)

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

Yes (1) No (2)

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

Yes (1) No (2)

39. 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)
d. Gastric electrical stimulator:	(1)	(2)

40. Is a gastric electrical stimulator present:

Yes (1) No (2)

41.

a. Is gastric electrical stimulator currently turned on:

Yes (1) No (2)

41. 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

42. Since the date in item 8, has the patient used insulin for diabetes:

Yes (1) No (2)

43.

a. Since the date in item 8, has the patient used an insulin pump:

Yes (1) No (2)

b. Is the patient currently using an insulin pump:

Yes (1) No (2)

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

Yes (1) No (2)

44.

If yes or unsure, check all that apply):

a. Acarbose (Precose): (1)

b. Acetohexamide (Dymelor): (1)

c. Chlorpropamide (Diabinese): (1)

d. Exenetide (Byetta, Bydureon): (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. Pramlintide (Symlin): (1)

m. Repaglinide (Prandin): (1)

n. Rosiglitazone (Avandia): (1)

o. Sitagliptin (Januvia): (1)

p. Tolazamide (Tolinase): (1)

q. Tolbutamide (Orinase): (1)

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

_____
specify

44. Since the date in item 8, has the patient taken any anti-hyperlipidemic medications:

Yes (1) No (2)

45. ___

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

a. HMG-COA reductase inhibitors (Atorvastatin [Lipitor], Simvastatin [Zocor], Rosuvastatin [Crestor], Fluvastatin sodium [Lescol], Lovastatin [Mevacor], Pravastatin sodium [Pravachol]):, (1)

b. Bile acid sequestrant (Colestipol hydrochloride [Colestid]): (1)

c. Fibric acid (Gemfibrozil [Lopid], Fenofibrate [Tricor]): (1)

d. Nicotinic acid (Niaspan): (1)

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

_____
specify

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

Yes (1) No (2)

46. ___

(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

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

Yes (1) No (2)

47. ___

(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

47. Since the date in item 8, has the patient taken any cardiovascular/ antihypertensive medications: Yes (1) No (2)

48.

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

a. Class III antiarrhythmic agent (Amiodarone [Pacerone]): (1)

b. Dihydropyridine calcium channel blocker (Amlodipine besylate [Norvasc], Felodipine [Plendil], Nifedipine [Adalat, Procardia]): (1)

c. Beta$_1$-adrenergic blocker (Atenolol [Tenormin], Metoprolol [Lopressor]: (1)

d. Non-selective beta blocker (Caryedilol [Coreg], Propranolol [Inderal], Timolol maleate [Blocadren]): (1)

e. Angiotensin-converting-enzyme inhibitors (Benazepril [Lotensin], Captopril [Capoten], Enalapril [Vasotec], Lisinopril [Prinivil, Zestril], Ramipril [Altace], Quinapril [Accupril]): (1)

f. Alpha-2 adrenergic agonist (Clonidine [Catapres]): (1)

g. Digoxin (Lanoxin): (1)

h. Diltiazem (Cardizem): (1)

i. Alpha-1 adrenergic blocker (Doxazosin [Cardura], Terazosin [Hytrin]): (1)

j. Furosemide (Lasix): (1)

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

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

m. Angiotensin II receptor antagonist (Losartan potassium [Cozaar], Valsartan [Diovan], Candesartan [Atacand]): (1)

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

o. Verapamil (Calan): (1)

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

_____
specify

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

_____
specify

48. 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)

49.

(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. Androgens (Fluoxymesterone [Android-F, Halotestin], Methyltestosterone [Android], Nandrolone [Deca-Durabolin, Hybolin Decanoate, Kabolin]): (1)

g. Progestins (Norethindrone [Micronor], Progesterone [Prometrium], Norgestrel [Ovrette], Levonorgestrel [Norplant], Medroxyprogesterone [Cycrin, Provera], Megestrol [Megace]): (1)

h. Combination 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)

i. Synthetic anabolic steroids (Oxandrolone [Oxandrin], Oxymetholone [Anadrol]): (1)

j. Selective estrogen receptor modulator (Raloxifene [Evista], Tamoxifen [Nolvadex]): (1)

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

specify

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

specify

J. Relevant medication use

For items 49-57: *Have the patient use flashcard #9a to indicate the frequency of use and flashcard #9b to indicate the perceived benefit for gastroparesis symptoms for each medication he/she uses/used*

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

Yes (1) No (2)

50. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Antacids, *(specify):*	___	___
specify		
b. Cimetidine (Tagamet):	___	___
c. Dexlansoprazole (Dexilant):	___	___
d. Esomeprazole (Nexium):	___	___
e. Famotidine (Pepcid):	___	___
f. Lansoprazole (Prevacid):	___	___
g. Nizatidine (Axid):	___	___
h. Omeprazole (Prilosec, Zegerid):	___	___
i. Pantoprazole (Protonix):	___	___
j. Rabeprazole (Aciphex):	___	___
k. Ranitidine (Zantac):	___	___
l. Other *(specify):*	___	___
specify		
m. Other *(specify):*	___	___
specify		

50. Since the date in item 8, has the patient taken any prokinetic medications:

Yes (1) No (2)

51. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Azithromycin (Zithromax):	___	___
b. Bethanechol (Duvoid, Urecholine):	___	___
c. Clarithromycin (Biaxin):	___	___
d. Domperidone (Motilium):	___	___
e. Erythromycin:	___	___
f. Metoclopramide (Reglan):	___	___
g. Other *(specify):*	___	___
specify		
h. Other *(specify):*	___	___
specify		

51. Since the date in item 8, has the patient had Botox injected into the pylorus for his/her gastroparesis symptoms:

Yes (1) No (2)

52. ___

a. Perceived benefit *(use flashcard #9b):* ___ (0-5)

b. Number of weeks since last injection: ___ ___ (00-48)

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

Yes (1) No (2)

53.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Prochlorperazine (Compazine):	____	____
b. Promethazine (Pentazine, Phenergan):	____	____
c. Trimethobenzamide (Benzacot, Stemetic, Tigan):	____	____
d. Meclizine (Antivert):	____	____
e. Serotonin (5-HT3) antagonists (Ondansetron [Zofran], Tropisetron [Navoban], Granisetron [Kytril Sancuso Patch], Palonosetron [Aloxi], Dolasetron [Anzemet]):	____	____
f. Neurokinin-1 receptor antagonists (Aprepitant [Emend]):	____	____
g. Tricyclic antidepressants (Amitriptyline [Elavil], Desipramine [Norpramin], Imipramine [Tofranil], Nortriptyline [Aventyl, Pamelor]):	____	____
h. Dronabinol (Marinol):	____	____
i. Tetracylcic antidepressants (Mirtazapine [Remeron]):	____	____
j. Bupropion (Wellbutrin):	____	____
k. Selective Serotonin Reuptake Inhibitors (SSRI)[Citalopram (Celexa), Escitalopram (Lexapro), Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft)]:	____	____
l. Venlafaxine (Effexor):	____	____
m. Anxiolytic (Buspirone [BuSpar]):	____	____
n. Chlordiazepoxide (Librax):	____	____
o. Benzodiazepines (Lorazepam [Ativan], Alprazolam [Xanax], Diazepam [Valium], Oxazepam [Serax], Clonazepam [Klonopin], Temazepam [Restoril, Temaz], Flurazepam):	____	____
p. Meprobamate:	____	____
q. Quetiapine fumarate (Seroquel):	____	____
r. Other *(specify):*	____	____
specify		
s. Other *(specify):*	____	____
specify		

53. Since the date in item 8, has the patient used any of the following medications for constipation:

Yes (1) No (2)

54.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Polyethylene glycol (Miralax):	____	____
b. Lubiprostone (Amitiza):	____	____
c. Lactulose:	____	____
d. Linaclotide (Linzess):	____	____
e. Bisacodyl (Dulcolax):	____	____
f. Methylnaltrexone (Relistor):	____	____
g. Colchicine (Colcrys):	____	____
h. Misoprostol (Cytotec):	____	____
i. Prucalopride (Resolar):	____	____
j. Other *(specify):*	____	____
specify		

54. Since the date in item 8, has the patient taken any pain relieving, analgesics, non-steroidal anti-inflammatory, or aspirin containing medications (non-narcotic) either regular usage or as needed basis (prn):

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

55. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Acetaminophen (Tylenol):	___	___
b. Aspirin - 325 mg:	___	___
c. Celecoxib (Celebrex):	___	___
d. Ibuprofen (Advil, Motrin):	___	___
e. Indomethacin (Indocin):	___	___
f. Naproxen (Aleve, Naprosyn):	___	___
g. Other *(specify):*	___	___
specify		
h. Other *(specify):*	___	___
specify		
i. Other *(specify):*	___	___
specify		

55. Since the date in item 8, has the patient taken any narcotic pain medications:

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

57. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Acetaminophen (30 mg)/ codeine phosphate (Tylenol #3):	___	___
b. Acetaminophen (60 mg)/ codeine phosphate (Tylenol #4):	___	___
c. Acetaminophen/hydrocodone bitartrate (Lortab, Norco, Vicodin):	___	___
d. Acetaminophen/oxycodone hydrochloride (Percocet, Tylox):	___	___
e. Aspirin/oxycodone hydrochloride (Percodan):	___	___
f. Buprenorphine (Butrans patch):	___	___
g. Butalbital/acetaminophen/ caffeine (Esgic - Plus):	___	___
h. Fentanyl transdermal (Duragesic patch):	___	___
i. Fentanyl oral (Abstral, Actiq, Fentora):	___	___
j. Hydromorphone hydrochloride (Dilaudid):	___	___
k. Oxycodone hydrochloride (OxyContin):	___	___
l. Methadone hydrochloride:	___	___
m. Morphine sulfate:	___	___
n. Pentazocine (Talacen):	___	___
o. Tapentadol (Nycynta):	___	___
p. Tramadol HCl (Ultram/ Ultracet):	___	___
q. Other *(specify):*	___	___
specify		

56. 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. Back pain: (1)

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

_____
specify

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

Yes (1) No (2)

58. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Duloxetine (Cymbalta):	____	____
b. Gabapentin (Neurontin):	____	____
c. Pregabalin (Lyrica):	____	____
d. Other *(specify):*	____	____

_____
specify

K. Alternative therapies

For item 58: *Have the patient use flashcard #9a to indicate the frequency of use and flashcard #9b to indicate perceived benefit for gastroparesis symptoms for each medication he/she uses/used*

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

Yes (1) No (2)

59. ___

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Probiotic #1 *(specify):*	____	____
_____ specify		
b. Probiotic #2 *(specify):*	____	____
_____ specify		
c. Herbal supplement #1 *(specify):*	____	____
_____ specify		
d. Herbal supplement #2 *(specify):*	____	____
_____ specify		
e. Herbal supplement #3 *(specify):*	____	____
_____ specify		
f. Acupuncture:	____	____
g. Acupressure bands/bracelets:	____	____
h. Reflexology:	____	____
i. Hypnotherapy:	____	____
j. Therapeutic Massage:	____	____
k. Other *(specify):*	____	____
_____ specify		

59. Since the date in item 8, has the patient used marijuana:

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

60. ___

(If yes, use flashcards #9a and 9b to answer items 59 a and b):

a. Frequency of use *(1-6):* ____

b. Perceived benefit *(0-5):* ____

L. Administrative information

60. Study Physician PIN: ____ ____ ____

61. Study Physician signature:

_____

62. Clinical Coordinator PIN: ____ ____ ____

63. Clinical Coordinator signature:

_____

64. Date form reviewed:

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

Gastroparesis Registry 2

FQ - Food Questionnaire Documentation

Purpose: To document completion of the food questionnaire.
When: Screening visit s and follow-up visits f048, f096, f144, f192 and f240.
Administered by: Clinical Coordinator.
Instructions: This form documents completion of the Block 2005 food questionnaire. The completed Block 2005 food questionnaires should be sent to the DCC once a month with the completed TB form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(Date Block 2005 food questionnaire was completed):*

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: f q 1

7. Study: GpR 2 5

B. Administration of food questionnaire

8. Form copy of label applied to the Block 2005 food questionnaire:

GpR2 Form FQ
Pt: 9999,xyz
Visit: vvvv
Date: _____

C. Administrative information

9. Clinical Coordinator PIN: ____ ____ ____

10. Clinical Coordinator signature:

_____

11. Date form reviewed:

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

Gastroparesis Registry 2

GE - Gastric Emptying Test Documentation - Screening only

Purpose: Record results of the combined solid and liquid phase gastric emptying scintigraphy to determine eligibility.

When: Screening visit s. The gastric emptying scintigraphy must have been performed at a GpCRC clinical center. The screening scintigraphy must be within 6 months of registration date.

Administered by: Study Physician and Clinical Coordinator.

Instructions: Information not included in the report (ie, blood glucose) should be gathered directly from the patient before or immediately after the test if possible. For quality control, the staff technologist records how long it takes the participant to consume the meal and how much they consume. The patient should ingest the whole meal. If the patient cannot eat the entire meal, at least 50% of each component should be consumed for the test. If the patient vomits part of the meal at any time during the test, this should be indicated on the report in item 17, 22, or 27. Complete section C items 13-17 only if the gastric emptying scintigraphy of solids and liquids was done as a combined test. Complete sections D and E items 18-27 if the gastric emptying test of solids and liquids were performed on different days. The Study Physician should complete the remainder of this form (items 28-32) using the report(s) generated by the gastric emptying scintigraphy. If an Elig or STOP is reached for any item then STOP filling out form and do not data enter the form. If CAUTION responses are checked for any item, further review is necessary to determine eligibility status.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

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

5. Visit code: s ____ ____ ____

6. Form & revision: g e 1

7. Study: GpR 2 5

B. Gastric Emptying Scintigraphy Test

8. Is the patient allergic to eggs:

Yes (* 1) No (2)

Elig

**Patient is ineligible. Key the EN form to document reason for ineligibility*

9. Did the patient fast at least 8 hours prior to the test:

Yes (1) No (* 2)

STOP

**Patient must be fasting; test must be rescheduled.*

10. Is the patient diabetic:

Yes (1) No (2)

11.

a. What was the blood glucose prior to the GES:

____ ____ ____
mg/dL

b. Was the patient's blood glucose level < 270 mg/dL:

Yes (1) No (* 2)

STOP

**Glucose must be less than 270 mg/dL; test must be rescheduled.*

11. Did the patient stop using proton pump inhibitors, histamine 2 antagonists, prokinetics, narcotics, anticholinergics and cannabinoids for 3 days prior to the test:

Yes (1) No (* 2)

STOP

**Test must be rescheduled.*

12. Is this a combined radiolabeled solid and liquids gastric emptying test:

Yes (*1)
**Complete items 13-17.*

No, solid and liquid emptying tests were performed on different days (†2)
→ **18.**

†Complete items 18-28.

C. Combined solids and liquids scintigraphy

Complete items 13-17 only if the gastric emptying scintigraphy of solids and liquids was done as a combined test.

13. Date of combined labeled solid and liquid gastric emptying scintigraphy:

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

a. Is the date within 6 months of registration:

Yes (1) No (*2)
→ STOP

**Test must be rescheduled.*

14. Meal labeled with T_c-99_m given for test:

Egg Beaters with 2 pieces of bread/toast and 1 oz of jam (1)
Generic low-fat egg whites with 2 pieces of bread/toast and 1 oz of jam (2)
Other *(specify)* (*3)

_____
specify

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

15. Amount of meal and water 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. Indium labeled water *(check only one):*

125 mL = 100% (1)
112 mL = 90% (2)
94 mL = 75% (3)
63 mL = 50% (4)
41 mL = 33% (*5)
31 mL = 25% (*6)
13 mL = 10% (*7)
0 mL = 0% (*8)
Unknown (9)

**Caution: Test may not be clinically diagnostic for < 50% of the meal or water consumed as a smaller meal will empty more rapidly. Abnormal gastric retention for < 50% of the meal or water can still be considered diagnostic for delayed gastric emptying.*

16. Approximate time it took for participant to consume the test meal

0-5 min (1)
6-10 min (2)
11-15 min (3)
16-30 min (4)
> 30 min (5)
Unknown (6)

17. Did the patient vomit the meal or water at any time during the tests:

Yes (*1) No (2) → **28.**

a. How many minutes into the test did the vomiting occur:

____ ____ ____
min

Description of vomitus:

b. Liquid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

c. Solid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

**Caution: If the amount of the meal or water vomited is large; test may not be clinically diagnostic.*

Go to item 28.

Complete items 18-27 if the gastric emptying test of solids and liquids were performed on different days

D. Gastric emptying of solids

18. Date of gastric emptying of <u>labeled</u> solids scintigraphy *(patient consumes with <u>un</u>labeled liquid):*

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

a. Is the date within 6 months of registration:

Yes (1) No (*2) → STOP

**Test must be rescheduled.*

19. T_c-99_m labeled meal given for test:

Egg Beaters with 2 pieces of bread/toast and 1 oz of jam	(1)
Generic low-fat egg whites with 2 pieces of bread/toast and 1 oz of jam	(*2)
Other *(specify)*	(*3)

_____
specify

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

20. Amount of labeled meal and unlabeled water consumed

a. T_c-99_m labeled meal *(check only one):*

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

b. Unlabeled water *(check only one):*

125 mL = 100%	(1)
112 mL = 90%	(2)
94 mL = 75%	(3)
63 mL = 50%	(4)
41 mL = 33%	(*5)
31 mL = 25%	(*6)
13 mL = 10%	(*7)
0 mL = 0%	(*8)
Unknown	(9)

**Caution: Test may not be clinically diagnostic for < 50% of the meal or water consumed as a smaller meal will empty more rapidly. Abnormal gastric retention for < 50% of the meal or water can still be considered diagnostic for delayed gastric emptying.*

21. Approximate time it took for participant to consume the test meal

0-5 min	(1)
6-10 min	(2)
11-15 min	(3)
16-30 min	(4)
> 30 min	(5)
Unknown	(6)

22. Did the patient vomit the meal or water at any time during the tests:

Yes (*1) No (2) → 23.

a. How many minutes into the test did the vomiting occur: ____ ____ ____ min

Description of vomitus:

b. Liquid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(4)

c. Solid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

**Caution: Test may not be clinically diagnostic if the amount of liquid vomited is large.*

E. Gastric emptying of liquids

**Note: If gastric emptying of liquids is performed on a different day than gastric emptying of solids, the patient consumes an <u>unlabeled</u> Egg Beaters® meal (Egg Beaters®, bread, jam) with radiolabeled water.*

23. Date of gastric emptying of <u>labeled</u> liquids scintigraphy *(patient consumes an <u>unlabeled</u> meal):*

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

a. Is the date within 6 months of registration:

Yes (1) No (*2) → STOP

**Test must be rescheduled.*

24. Unlabeled meal given for test:

Egg Beaters with 2 pieces of bread/toast and 1 oz of jam	(1)
Generic low-fat egg whites with 2 pieces of bread/toast and 1 oz of jam	(2)
Other *(specify)*	(*3)

_____
specify

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

25. Amount of unlabeled meal and Indium labeled water consumed

a. Unlabeled meal *(check only one):*

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

b. Indium labeled water *(check only one):*

125 mL = 100%	(1)
112 mL = 90%	(2)
94 mL = 75%	(3)
63 mL = 50%	(4)
41 mL = 33%	(*5)
31 mL = 25%	(*6)
13 mL = 10%	(*7)
0 mL = 0%	(*8)
Unknown	(9)

**Caution: Test may not be clinically diagnostic for < 50% of the meal or water consumed as a smaller meal will empty more rapidly. Abnormal gastric retention for < 50% of the meal or water can still be considered diagnostic for delayed gastric emptying.*

26. Approximate time it took for participant to consume the test meal

0-5 min	(1)
6-10 min	(2)
11-15 min	(3)
16-30 min	(4)
> 30 min	(5)
Unknown	(6)

27. Did the patient vomit the meal or water at any time during the tests:

Yes (*1) No (2) → **28.**

a. How many minutes into the test did the vomiting occur: ____ ____ ____ min

Description of vomitus:

b. Liquid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

c. Solid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(4)

**Caution: Test may not be clinically diagnostic if the amount of liquid vomited is large.*

F. Scintigraphy results

28. Percent of gastric retention of solids *(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, 4 hour time points are required.*

29. Percent of gastric retention of liquids *(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, 3 and 4 hour time points are optional, but should be obtained if possible. The 0 minutes, 1 and 2 hour time points are required.*

30. Interpretation of gastric emptying scintigraphy:

_____

_____

_____

31. Comments on the gastric emptying scintigraphy:

_____

_____

_____

_____

G. Results summary

32. Results of gastric emptying scintigraphy

a. Was the patient able to complete gastric emptying scintigraphy test:

Yes (1) No (2) → Elig (5)

b. Did patient have abnormal 2-hour or 4-hour values on the gastric emptying of solids scintigraphy:

Yes (1) No (2)

c. Was 2-hour value greater than 60%:

Yes (1) No (2)

d. Was 4-hour value greater than 10%:

Yes (1) No (2)

H. Data Coordinating Center use

33. Study Physician PIN: ____ ____ ____

34. Study Physician signature:

_____

35. Clinical Coordinator PIN: ____ ____ ____

36. Clinical Coordinator signature:

_____

37. Date form reviewed:

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

38. Date the images were sent to DCC:

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

Per GpR 2 protocol, the gastric emptying tests will be performed at the GpCRC centers and the images saved to a CD or DVD. The centers will need to de-identify the patient information using available software and send the images every 3 months in DICOM format to the DCC with a completed TS form.

Gastroparesis Registry 2

GT - Gastric Emptying Test Documentation - Follow-up

Purpose: Record results of the solid phase gastric emptying scintigraphy performed during follow-up.

When: Follow-up visit f048. If patient has an additional gastric emptying scintigraphy during study participation, results should be recorded on the GT form using the visit code of the window that is open. The gastric emptying scintigraphy must be performed at a GpCRC clinical center.

Administered by: Study Physician and Clinical Coordinator.

Instructions: For quality control, the staff technologist records how long it takes the participant to consume the meal and how much they consume. The patient should ingest the whole meal. If the patient cannot eat the entire meal, at least 50% of each component should be consumed for the test. If the patient vomits part of the meal at any time during the test, this should be indicated on the report in item 17. If a STOP is reached for any item then STOP filling out and do not enter the form. The Study Physician should complete the remainder of this form (items 13-20) using the report generated by the gastric emptying scintigraphy. Information not included in the test report should be gathered directly from the patient before or immediately after the test if possible.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: g t 1

7. Study: GpR 2 5

B. Gastric Emptying Scintigraphy Test

8. Is there any possibility that the participant is pregnant:

Yes (*1) → **21.**
No (2)
Not applicable (3)

**Test must be rescheduled after pregnancy.*

9. Did the patient fast at least 8 hours prior to the test:

Yes (1) No (*2) → STOP

**Patient must be fasting; test must be rescheduled.*

10. Is the patient diabetic:

Yes (1) No (2) → **11.**

a. Is the patients blood glucose level < 270 mg/dL:

Yes (1) No (*2) → STOP

**Glucose must be less than 270 mg/dL; test must be rescheduled.*

11. Did the patient stop using proton pump inhibitors, histamine 2 antagonists, prokinetics, narcotics, anticholinergics and cannabinoids for 3 days prior to the test:

Yes (1) No (*2) → STOP

**Test must be rescheduled.*

12. Date of gastric emptying of solids scintigraphy:

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

13. Meal given for test:

Egg Beaters with 2 pieces of bread/toast and 1 oz of jam (1)
Generic low-fat egg whites with 2 pieces of bread/toast and 1 oz of jam (2)
Other *(specify)* (*3)

_____
specify

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

14. Best visual estimate of the amount of meal consumed *(check only one):*

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

15. Best visual estimate of the amount of water consumed *(check only one):*

125 mL = 100%	(1)
112 mL = 90%	(2)
94 mL = 75%	(3)
63 mL = 50%	(4)
41 mL = 33%	(*5)
31 mL = 25%	(*1)
13 mL = 10%	(*7)
0 mL = 0%	(*8)
Unknown	(9)

**Caution: Test may not be clinically diagnostic for < 50% of the meal or water consumed as a smaller meal will empty more rapidly. Abnormal gastric retention for < 50% of the meal can still be considered diagnostic however for delayed gastric emptying.*

16. Approximate time it took for participant to consume the test meal

0-5 min	(1)
6-10 min	(2)
11-15 min	(3)
16-30 min	(4)
> 30 min	(5)
Unknown	(6)

17. Did the patient vomit the meal or water at any time during the test:

Yes (1) No (*2)

18.

a. How many minutes into the test did the vomiting occur:

____ ____ ____
min

Description of vomitus:

b. Liquid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

c. Solid portion:

None	(1)
Small	(2)
Moderate	(3)
Large	(*4)

**Caution: Test may not be clinically diagnostic if the amount of liquid vomit is large.*

C. Scintigraphy results

18. Percent of gastric retention of solids *(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, 4 hour time points are required.*

19. Interpretation of gastric emptying scintigraphy:

_____

_____

_____

20. Comments on the gastric emptying scintigraphy:

_____

_____

_____

_____

D. Data Coordinating Center use

21. Study Physician PIN: ____ ____ ____

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ____ ____ ____

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

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

26. Date the images were sent to DCC:

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

Per GpR 2 protocol, the gastric emptying tests will be performed at the GpCRC centers and the images saved to a CD or DVD. The centers will need to de-identify the patient information using available software and send the images every 3 months in DICOM format to the DCC with the completed TS form.

Gastroparesis Registry 2

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 s and as needed at follow-up visits f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.

Administered by: Study Physician and Clinical Coordinator.

Instructions: All laboratory test results are **required** during screening. 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 EXIT is reached in item 33 or in item 47, the patient is NOT eligible and cannot enroll in the Gastroparesis Registry 2. 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: l r 1

7. Study: GpR 2 5

B. Etiologic lab tests

8. Are lab results available for ANA and CRP at this visit:

Yes (1) No (2)

12.

9. Date of blood draw for ANA and CRP:

____ ____–____ ____ ____–____ ____
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 GpR 2 visit time window guide). These tests are optional during follow-up visits.

10. Antinuclear antibody (ANA):

Positive (* 1)

Negative (2)

11.

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

a. Titer *(record only the denominator):*

1: ____ ____ ____ ____

b. Units: ____ ____ • ____

11. High sensitivity 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.

C. Vitamins

12. Are lab results available for vitamins at this visit:

Yes (1) No (2)

16.

13. Date of blood draw for vitamins:

____ ____–____ ____ ____–____ ____
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 GpR 2 visit time window guide).

14. Vitamin B12: ____ ____ ____ ____
pg/mL

15. 25-Hydroxy Vitamin D total: ____ ____ ____
ng/mL

16. Are HbA1c results required at this time:

Yes, baseline visit (1)
Yes, diabetic visit (2)
No, not required but result is available (3)
No, not required at this time (4)

17.

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

a. 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 GpR 2 visit time window guide).

b. HbA1c: ____ ____ • ____ %

D. Hematology

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

Yes (1) No (2)

25.

18. Date of blood draw for complete blood count:

____ ____–____ ____ ____–____ ____
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 GpR 2 visit time window guide). These tests are optional during follow-up visits.

19. White blood cell count (WBC):

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

20. Red blood cell count (RBC):

____ ____ ____ • ____
10^6 cells/ µL (million cells/mL)

21. Hemoglobin: ____ ____ • ____ g/dL

22. Hematocrit: ____ ____ • ____ %

a. Mean corpuscular volume:

____ ____ ____ • ____ fL

23. Platelet count: ____ ____ ____,____ ____ ____ cells/ µL

24. Erythrocyte sedimentation rate ____ ____ ____ mm/hr

E. Chemistries and TSH

25. Are lab results available for chemistry panel at this visit:

Yes (1) No (2)

36.

26. 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 GpR 2 visit time window guide). These tests are optional during follow-up visits.

27. Sodium: ____ ____ ____ mEq/L

28. Potassium: ____ ____ • ____ mEq/L

29. Chloride: ____ ____ ____ mEq/L

30. Carbon dioxide: ____ ____ • ____ mEq/L

31. Calcium: ____ ____ • ____ mg/dL

32. Blood urea nitrogen (BUN): ____ ____ mg/dL

33. Creatinine: ____ ____ • ____ mg/dL

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

Yes (1) No (2)

Elig

If Yes, the patient is ineligible and cannot be enrolled in the GpR 2. This form should not be keyed to the data system but retained by the study site. Refer to SOP I regarding repeating this test.

34. Serum glucose: ____ ____ ____ mg/dL

35. Thyroid stimulating hormone (TSH):

___ ___ • ___ ___
µIU/mL or µIU/L

F. Liver panel

36. Are lab results available for liver panel at this visit:

Yes (1) No (2)
44.

37. Date of blood draw for liver 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 GpR 2 visit time window guide). These tests are optional during follow-up visits.

38. Total protein: ___ ___ • ___ ___
g/dL

39. Albumin: ___ ___ • ___ ___
g/dL

40. Alkaline phosphatase ___ ___ ___
U/L

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

42. Alanine aminotransferase (ALT):

___ ___ ___
U/L

43. Aspartate aminotransferase (AST):

___ ___ ___
U/L

G. Lipid profile

44. Are lab results available for lipids at this visit:

Yes (1) No (2)
46.

45. Date of blood draw for lipid profile:

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

Date must be within the required time window: within 16 weeks of screening or in the time window for the follow- up visit (check the patient's GpR 2 visit time window guide).

a. Triglycerides: ___ ___ ___ ___
mg/dL

b. Total cholesterol: ___ ___ ___
mg/dL

c. HDL cholesterol: ___ ___ ___
mg/dL

d. LDL cholesterol*: ___ ___ ___
mg/dL

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

H. Eligibility check

46. Is this screening visit s:

Yes (1) No (2)
48.

47. 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 2.

I. Administrative information

48. Study Physician PIN: ___ ___ ___

49. Study Physician signature:

_____

50. Clinical Coordinator PIN: ___ ___ ___

51. Clinical Coordinator signature:

_____

52. Date form reviewed:

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

Gastroparesis Registry 2

NV – Nausea Profile and Vomiting Questionnaire

Purpose: To obtain the patient's frequency and intensity of symptoms due to nausea and/or vomiting.
When: At screening visit s and follow-up visits f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO labels to pages 2-7 before giving the questionnaire to the patient for completion. 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 2-7, and the Clinical Coordinator should complete section B.

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: n v 1

7. Study: GpR 2 **5**

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

8. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature:

_____

9. Date form reviewed:

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

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

(Items 1-9 are reserved for clinic use)

This questionnaire asks you about the nausea and vomiting you experience.

NAUSEA

10. Do you experience nausea as a symptom?

Yes (1) No (2)

→ **32.**

11. When your nausea occurs, how long does your nausea last *(check only one)*:

Several minutes . . . . . (1)
About 30 minutes . . . . . (2)
About 1 hour . . . . . (3)
Several hours . . . . . (4)
Most of the day . . . . . (5)

12. Timing of nausea

	Yes	No	Sometimes
a. My nausea is worse in the morning before eating:	(1)	(2)	(3)
b. My nausea is worse in the evening:	(1)	(2)	(3)

c. My nausea typically occurs *(check only one)*:

During eating . . . . . (1)
Within 15 minutes after eating . . . . . (2)
15 to 30 minutes after eating . . . . . (3)
30 to 60 minutes after eating . . . . . (4)
1-3 hours after eating . . . . . (5)
More than 3 hours after eating . . . . . (6)
All of the above . . . . . (7)
Unrelated to eating . . . . . (8)

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

13. What type of meal typically provokes your nausea *(check all that apply)*

a. High fat meal: (1)
b. Dairy products: (1)
c. Vegetables or high-fiber meal: (1)
d. Spicy meal: (1)
e. None of the above: (1)

14. What makes your nausea better or worse

	Yes	No	Sometimes
a. My nausea increases during and/or after eating:	(1)	(2)	(3)
b. My nausea increases when I get hungry:	(1)	(2)	(3)
c. My nausea decreases when I get hungry:	(1)	(2)	(3)
d. My nausea increases when I ride in a car or bus:	(1)	(2)	(3)

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

NAUSEA PROFILE

Rate the degree to which each of the following statements describes how you feel when you experience nausea. Please circle the appropriate number for each description on the scale below with 0=not at all and 9=severely.

		0=Not at All									9= Severely
15.	I feel shaky:	0	1	2	3	4	5	6	7	8	9
16.	I feel upset:	0	1	2	3	4	5	6	7	8	9
17.	I feel lightheaded:	0	1	2	3	4	5	6	7	8	9
18.	I feel sick:	0	1	2	3	4	5	6	7	8	9
19.	I feel sweaty:	0	1	2	3	4	5	6	7	8	9
20.	I feel queasy:	0	1	2	3	4	5	6	7	8	9
21.	I feel worried:	0	1	2	3	4	5	6	7	8	9
22.	I feel hopeless:	0	1	2	3	4	5	6	7	8	9
23.	I feel fatigued/tired:	0	1	2	3	4	5	6	7	8	9
24.	I feel panicked:	0	1	2	3	4	5	6	7	8	9
25.	I feel nervous:	0	1	2	3	4	5	6	7	8	9
26.	I feel scared/afraid:	0	1	2	3	4	5	6	7	8	9
27.	I feel ill:	0	1	2	3	4	5	6	7	8	9
28.	I feel awareness/discomfort in my stomach:	0	1	2	3	4	5	6	7	8	9
29.	I feel as if I might vomit:	0	1	2	3	4	5	6	7	8	9
30.	I feel weak:	0	1	2	3	4	5	6	7	8	9
31.	I feel hot/warm:	0	1	2	3	4	5	6	7	8	9

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

VOMITING

32. Do you experience vomiting as a symptom?

Yes (1) No (2)

45.

33. When your vomiting occurs, how long does your vomiting last *(check only one)*:

Several minutes . . . . . (1)
About 30 minutes . . . . . (2)
About 1 hour . . . . . (3)
Several hours . . . . . (4)
Most of the day . . . . . (5)

34. Timing of vomiting

	Yes	No	Sometimes
a. My vomiting occurs in the morning before eating:	(1)	(2)	(3)
b. I wake up at night vomiting:	(1)	(2)	(3)

c. My vomiting typically occurs *(check only one)*:

During eating . . . . . (1)
Within 15 minutes after eating . . . . . (2)
15 to 30 minutes after eating . . . . . (3)
30 to 60 minutes after eating . . . . . (4)
1-3 hours after eating . . . . . (5)
More than 3 hours after eating . . . . . (6)
All of the above . . . . . (7)
Unrelated to eating . . . . . (8)

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

35. When I vomit, the material vomited is predominantly *(check only one)*:

Saliva . . . . . (1)
Water . . . . . (2)
Yellow or green liquid that tastes bitter . . . (3)
Partially digested food . . . . . (4)
Undigested food . . . . . (5)
Nothing (retching or dry heaving) . . . . . (6)

36. Do you experience retching or dry heaving before, during or after vomiting

Always . . . . . (1)
Often . . . . . (2)
Sometimes . . . . . (3)
Never (vomiting occurs without effort) . . . (4)

37. Do you experience nausea before you vomit:

Always . . . . . (1)
Often . . . . . (2)
Sometimes . . . . . (3)
Never (vomiting occurs without nausea) . . (4)

39.

38. Does vomiting relieve your nausea?

Always . . . . . (1)
Often . . . . . (2)
Sometimes . . . . . (3)
Never (vomiting occurs without nausea) . . (4)

39. Do you vomit even if you have not eaten or drunk anything all day?

Yes . . . . . (1)
Sometimes . . . . . (2)
No . . . . . (3)

NV - Nausea Profile and Vomiting Questionnaire

Affix label here

Patient ID: __ __ __ __
Pt code: __ __ __
Visit code: __ __ __ __

40. Do you vomit even if all you have had is water?

Yes . . . . . (1)
Sometimes . . . . . (2)
No . . . . . (3)

41. What makes your vomiting better or worse?

	Yes	Sometimes	No
a. My vomiting is worsened by eating:	(1)	(2)	(3)
b. My vomiting improves with eating:	(1)	(2)	(3)
c. Does the smell of food make you vomit:	(1)	(2)	(3)

42. What type of meal typically provokes your vomiting *(check all that apply)*

a. High fat meal: (1)
b. Dairy products: (1)
c. Vegetables or high-fiber meal: (1)
d. Spicy meal: (1)
e. None of the above: (1)

43. In the last 24 hours, how many times have you vomited: _____ _____

44. Over the last 24 hours, how would you grade the severity of your vomiting:

None . . . . . (1)
Mild . . . . . (2)
Moderate . . . . . (3)
Severe . . . . . (4)
Very severe . . . . . (5)

45. Today's date: _____

Gastroparesis Registry 2

PD - Physical Activity Documentation

Purpose: To document completion of the Block Energy Expenditure Survey.
When: Screening visit s and follow-up visits f048, f096, f144, f192 and f240.
Administered by: Clinical Coordinator.
Instructions: This form documents completion of the Block Energy Expenditure Survey . The completed Block Energy Expenditure Survey should be sent to the DCC once a month with the completed EQ form.

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date form completed *(Date Block Energy Expenditure Survey was completed):*

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: p d 1

7. Study: GpR 2 5

B. Administration of Block Energy Expenditure Survey

8. Form copy of label applied to the Block Energy Expenditure Survey:

GpR2 Form PD
Pt: 9999,xyz
Visit: vvvv

Date: _____

C. Administrative information

9. Clinical Coordinator PIN: ____ ____ ____

10. Clinical Coordinator signature:

_____

11. Date form reviewed:

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

Gastroparesis Registry 2

PE - Physical Examination

Purpose: Record detailed physical exam findings.

When: Screening visit s and follow-up visits f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.

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 2 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: GpR 2 5

B. Measurements

8. Weight *(shoes off)*

a. Weight: ____ ____ ____ • ____

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

9. Height *(shoes off)*

a. Height: ____ ____ ____ • ____

b. Units:
Inches (1)
Centimeters (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. Bruit: (1)
d. Succussion splash: (1)
e. Tenderness: (1)
f. Organomegaly: (1)
g. Other *(specify):* (1)

_____
specify

20. Liver and spleen:

Normal (1)
Abnormal (2)
→ **21.**

_____
specify

21. Nervous system:

Not performed (0)
Normal (1)
Abnormal (2)
→ **22.**

_____
specify

22. Other abnormalities noted:

Yes (1) No (2)
→ **23.**

_____
specify other abnormalities

D. Eligibility check

23. Is this a screening visit: Yes (1) No (2)
→ **25.**

24. Are all items on form completed: Yes (1) No (2)
→ **Elig**

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

Keyed: ( )

Gastroparesis Registry 2

PQ – Patient Health Questionnaire

Purpose: To obtain the patient's views of his/her health in the Gastroparesis Registry 2 study.
When: Screening visit s and follow-up visits f024, f048, f072, f096, f120, f144, f168, f192, f216 and f240.
Administered by: Self-administered, but Clinical Coordinator must be available at visits to answer questions and to review completed form.
Respondent: Patient.
Instructions: The Clinical Coordinator should complete section A and attach a MACO label to page 2 before giving the questionnaire to the patient for completion. The Clinical Coordinator should review the completed form questionnaire for missing responses and resolve any problems before the patient leaves the clinical center. Page 1 should be reattached to page 2, and the Clinical Coordinator should complete section B.

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 q 1

7. Study: GpR2 **5**

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

8. Clinical Coordinator

a. PIN: _____ _____ _____

b. Signature:

_____

9. Date form reviewed:

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

Affix label here

Patient ID: __ __ __ __

Pt code: __ __ __

Visit code: __ __ __ __

PQ - Patient Health Questionnaire

A 15-Item Somatic Symptom Severity Scale

(Items 1-9 are reserved for clinic use)

10. During the past 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered at all	**Bothered a little**	**Bothered a lot**
a. Stomach pain	(1)	(2)	(3)
b. Back pain	(1)	(2)	(3)
c. Pain in your arms, legs, or joints *(knees, hips, etc)*	(1)	(2)	(3)
d. Menstrual cramps or other problems with your periods *[Women only; record "n" if male]*	(1)	(2)	(3)
e. Headaches	(1)	(2)	(3)
f. Chest pain	(1)	(2)	(3)
g. Dizziness	(1)	(2)	(3)
h. Fainting spells	(1)	(2)	(3)
i. Feeling your heart pound or race	(1)	(2)	(3)
j. Shortness of breath	(1)	(2)	(3)
k. Pain or problems during sexual intercourse	(1)	(2)	(3)
l. Constipation, loose bowels, or diarrhea	(1)	(2)	(3)
m. Nausea, gas, or indigestion	(1)	(2)	(3)
n. Feeling tired or having low energy	(1)	(2)	(3)
o. Trouble sleeping	(1)	(2)	(3)

Thank you. Please return this questionnaire to the Clinical Coordinator.

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) (No 2) → E.Hg

** 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:

Yes (1) No (2)

22.

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

ST - EGG and Nutrient Meal Test

Purpose: To document symptoms and results of the nutrient meal test and electrogastrogram in patients with gastroparesis.
When: Screening visit.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient will respond to symptom evaluations on pages 2-10.
Instructions: The Clinical Coordinator should complete section A. The Clinical Coordinator will use pages 2-10 to obtain patient's responses during the test procedure. The visual analog scales on pages 2, 5, 6, 7, 8, 9, and 10 are 100 mm in length and should be measured from left to right with a metric (SI) ruler. Enter the value closest to the patient's vertical line in millimeters (0-100 mm) in items 11, 19, 20, 21, 22, 23, and 24. **Choose only whole minutes and do not select more than 15 minutes for the baseline period.** Using the EGG report, complete section G. The Study Physician and Clinical Coordinator should complete Section H. Attach a copy of the EGG report to this form. Save the raw digital EGG data to a USB flash drive.

A. Clinic, visit, and patient identification

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: s t 1

7. Study: GpR 2 5

8. Has the patient fasted since midnight:

Yes (1) No (*2) → Stop

* *Patient must be fasting; test must be re-scheduled.*

8a. Is the patient's blood glucose level <270 mg/dL:

Yes (1) No (*2) → Stop

** Glucose must be less than 270 mg/dL; test must be rescheduled.*

9. Has the patient stopped using proton pump inhibitors for 7 days:

Yes (1) No (*2) → Stop

** Test must be re-scheduled.*

10. Has the patient stopped using histamine 2 antagonists, prokinetics, narcotics, anticholinergics and cannabinoids for 3 days:

Yes (1) No (*2) → Stop

** Test must be rescheduled.*

B. Baseline Symptom Scores

11. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

C. Smart Bar® ingestion

Patient should consume the Smart Bar® within 10 minutes.
Patient may consume up to 50 mL of water with the Smart Bar®.

12. Time patient started consuming the Smart Bar®:

□□ : □□
(24-Hour clock)

13. Time patient finished the Smart Bar®:

□□ : □□
(24-Hour clock)

14. Volume of water ingested with Smart Bar®: __ __ __
(mL)

15. Amount of Smart Bar consumed *(check only one)*:

100%	(1)
90%	(2)
75%	(3)
50%	(4)
30%	(5)
25%	(6)
10%	(7)
0%	(8)

D. Smart Pill® ingestion

16. Does the patient have any of the following *(check all that apply)*

a. History of gastric bezoar: (1)
b. Disorder of swallowing: (1)
c. Suspected strictures, fistulas, or physiological GI obstruction: (1)
d. GI surgery within the past three months: (1)
e. Severe dysphagia to food or pills: (1)
f. Crohn's disease or diverticulitis: (1)
g. Uses an implanted or portable electro-mechanical medical device such as a cardiac pacemaker or infusion pump: (1)
h. Were any of the items above (16a-g) checked:

Yes (* 1) No (2)

If Yes → 19.

** If any of the above are checked, the Smart Pill® Capsule SHOULD NOT be administered*

17. Was the patient able to ingest the Smart Pill® Capsule:

Yes (1) No (2)

If No → 19.

17a. Time patient ingested the Smart Pill®:

□□ : □□
(24-Hour clock)

18. Volume of water ingested with Smart Pill®: __ __ __ (mL)

E. Post prandial Symptom Scores

19. SYMPTOMS – Immediately, 0 minutes AFTER Smart Bar®/Smart Pill® ingestion

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

20. SYMPTOMS -- 15 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

21. SYMPTOMS -- 30 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

22. SYMPTOMS -- 45 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

23. SYMPTOMS -- 60 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

24. SYMPTOMS -- 90 MINUTES AFTER finishing Smart Bar® (at end of EGG)

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __
mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __
mm

NONE — EXTREME

c. NAUSEA

__ __ __
mm

NONE — SEVERE

d. BLOATING

__ __ __
mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __
mm

NONE — SEVERE

F. Calibration

25. Measure the length of the line below and enter the total length in millimeters: __ __ __ mm

G. EGG Data (Note: The EGG signal analysis must be performed on a minimum of 4 consecutive, artifact-free minutes per period)

26. What was the duration of the baseline 0-15 minute time period analyzed: __ __ (min)

27. What was the duration of the post satiety test 0-15 minute time period analyzed: __ __ (min)

28. What was the duration of the post satiety 16-30 minute time period analyzed: __ __ (min)

29. What was the duration of the post satiety 31-45 minute time period analyzed: __ __ (min)

30. What was the duration of the post satiety 46-60 minute time period analyzed: __ __ (min)

31. What was the duration of the post satiety 61-90 minute time period analyzed: __ __ (min)

32. Distribution of average power by frequency region (as % of power in the 0-15 cpm range) *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline (15):	**a.** _ _ _ . _ _%	**b.** _ _ _ . _ _%	**c**. _ _ _ . _ _%	**d.** _ _ _ . _ _%
0-15 post:	**e.** _ _ _ . _ _%	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _%	**h.** _ _ _ . _ _%
16-30 post:	**i.** _ _ _ . _ _%	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _%	**l.** _ _ _ . _ _%
31-45 post:	**m.** _ _ _ . _ _%	**n.** _ _ _ . _ _ %	**o.** _ _ _ . _ _%	**p.** _ _ _ . _ _%
46-60 post:	**q.** _ _ _ . _ _%	**r.** _ _ _ . _ _ %	**s.** _ _ _ . _ _%	**t.** _ _ _ . _ _%
61-90 post:	**u.** _ _ _ . _ _%	**v.** _ _ _ . _ _ %	**w.** _ _ _ . _ _%	**x.** _ _ _ . _ _%

33. Ratios of average powers (POSTprandial/PREprandial) by frequency range *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
0-15 post satiety:	**a.** _ _ _ . _ _	**b.** _ _ _ . _ _	**c.** _ _ _ . _ _	**d.** _ _ _ . _ _
16-30 post satiety:	**e.** _ _ _ . _ _	**f.** _ _ _ . _ _	**g** _ _ _ . _ _	**h.** _ _ _ . _ _
31-45 post satiety:	**i.** _ _ _ . _ _	**j.** _ _ _ . _ _	**k.** _ _ _ . _ _	**l.** _ _ _ . _ _
46-60 post satiety:	**m.** _ _ _ . _ _	**n.** _ _ _ . _ _	**o.** _ _ _ . _ _	**p.** _ _ _ . _ _
61-90 post satiety:	**q.** _ _ _ . _ _	**r.** _ _ _ . _ _	**s.** _ _ _ . _ _	**t.** _ _ _ . _ _

Data rounding rules for 34:

To round data, examine the digits following the last position required on the form:

· If the first digit following the last data position required for the response is less than 5, leave the digit in the last data position required for the response unchanged, e.g., if you need to round to __.__ __, then 1.4232 rounds to 1.42 and 1.443 rounds to 1.44

· If the first digit following the last data position required for the response is 5 or more, round up the digit in the last data position required for the response, e.g., if you need to round to __.__ __, then 1.4252 rounds to 1.43 and 4.756 rounds to 4.76

34. Distribution of average power by frequency range *(use data rounding rules above for 34. a.-x.)*:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline:	**a.** _ . _ _ e+ _ _ _	**b.** _ . _ _ e+ _ _ _	**c**. _ . _ _ e+ _ _ _	**d.** _ . _ _e+_ _ _
0-15 post:	**e.** _ . _ _e+ _ _ _	**f.** _ . _ _ e+ _ _ _	**g.** _ . _ _ e+ _ _ _	**h.** _ . _ _e+ _ _ _
16-30 post:	**i.** _ . _ _e+ _ _ _	**j.** _ . _ _ e+ _ _ _	**k.** _ . _ _ e+ _ _ _	**l.** _ . _ _ e+ _ _ _
31-45 post:	**m.** _ . _ _e+ _ _ _	**n.** _ . _ _ e+ _ _ _	**o.** _ . _ _ e+ _ _ _	**p.** _ . _ _ e+ _ _ _
46-60 post:	**q.** _ . _ _e+ _ _ _	**r.** _ . _ _ e+ _ _ _	**s.** _ . _ _ e+ _ _ _	**t.** _ . _ _ e+ _ _ _
61-90 post:	**u.** _ . _ _e+ _ _ _	**v.** _ . _ _ e+ _ _ _	**w.** _ . _ _ e+ _ _ _	**x.** _ . _ _ e+ _ _ _

35. Average dominant frequency *(do not round the numbers; record as they appear on the report)*:

a. Baseline: _ _. _ _ cpm

b. 0-15 post: _ _. _ _ cpm

c. 16 -30 post: _ _. _ _ cpm

d. 31 -45 post: _ _. _ _ cpm

e. 46 -60 post: _ _. _ _ cpm

f. 61 -90 post: _ _. _ _ cpm

36. Percentage of time with the dominant EGG frequencies in the four frequency ranges:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline:	**a.** _ _ _ %	**b.** _ _ _ %	**c**. _ _ _ %	**d.** _ _ _ %
0-15 post :	**e.** _ _ _ %	**f.** _ _ _ %	**g.** _ _ _ %	**h.** _ _ _ %
16-30 post:	**i.** _ _ _ %	**j.** _ _ _ %	**k.** _ _ _ %	**l.** _ _ _ %
31-45 post:	**m.** _ _ _ %	**n.** _ _ _ %	**o.** _ _ _ %	**p.** _ _ _ %
46-60 post:	**q.** _ _ _ %	**r.** _ _ _ %	**s.** _ _ _ %	**t.** _ _ _ %
61-90 post:	**u.** _ _ _ %	**v.** _ _ _ %	**w.** _ _ _ %	**x.** _ _ _ %

H. Administrative information

37. Study Physician PIN: __ __ __

38. Study Physician signature:

_____

39. Clinical Coordinator PIN: __ __ __

40. Clinical Coordinator signature:

_____

41. Date form reviewed:

__ __-__ __ __-__ __
day mon year

Attach a copy of the EGG report to this form.

Gastroparesis Registry 2

Keyed: ( )

ST - EGG and Nutrient Meal Test

Purpose: To document symptoms and results of the nutrient meal test and electrogastrogram in patients with gastroparesis.
When: Screening visit.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient will respond to symptom evaluations on pages 2-10.
Instructions: Perform urine pregnancy test and document positive results in item 16h. Prior to the test, diabetic patients must perform a finger stick blood glucose reading. The Clinical Coordinator should complete section A. The Clinical Coordinator will use pages 2-10 to obtain patient's responses during the test procedure. The visual analog scales on pages 2, 5, 6, 7, 8, 9, and 10 are 100 mm in length and should be measured from left to right with a metric (SI) ruler. Enter the value closest to the patient's vertical line in millimeters (0-100 mm) in items 11, 19, 20, 21, 22, 23, and 24. **Choose only whole minutes and do not select more than 15 minutes for the baseline period.** Using the EGG report, complete section G. The Study Physician and Clinical Coordinator should complete Section H. Attach a copy of the EGG report to this form. Save the raw digital EGG data to a USB flash drive.

A. Clinic, visit, and patient identification

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: s t 2

7. Study: GpR 2 5

8. Has the patient fasted since midnight:

Yes	No
(1)	(* 2)

Stop

** Patient must be fasting; test must be re-scheduled.*

8a. Is the patient's blood glucose level <270 mg/dL:

Yes	(1)
No	(* 2)
NA/not diabetic	(3)

Stop

** Glucose must be less than 270 mg/dL; test must be rescheduled.*

9. Has the patient stopped using proton pump inhibitors for 7 days:

Yes	No
(1)	(* 2)

Stop

** Test must be re-scheduled.*

10. Has the patient stopped using histamine 2 antagonists, prokinetics, narcotics, anticholinergics and cannabinoids for 3 days:

Yes	No
(1)	(* 2)

Stop

** Test must be rescheduled.*

B. Baseline Symptom Scores

11. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

C. Smart Bar® ingestion

Patient should consume the Smart Bar® within 10 minutes.
Patient may consume up to 50 mL of water with the Smart Bar®.

12. Time patient started consuming the Smart Bar®:

□□ : □□
(24-Hour clock)

13. Time patient finished the Smart Bar®:

□□ : □□
(24-Hour clock)

14. Volume of water ingested with Smart Bar®: __ __ __
(mL)

15. Amount of Smart Bar consumed *(check only one)*:

100%	(1)
90%	(2)
75%	(3)
50%	(4)
30%	(5)
25%	(6)
10%	(7)
0%	(8)

D. Smart Pill® ingestion

16. Does the patient have any of the following *(check all that apply)*

a. History of gastric bezoar: (1)
b. Disorder of swallowing: (1)
c. Suspected strictures, fistulas, or physiological GI obstruction: (1)
d. GI surgery within the past three months: (1)
e. Severe dysphagia to food or pills: (1)
f. Crohn's disease or diverticulitis: (1)
g. Uses an implanted or portable electro-mechanical medical device such as a cardiac pacemaker or infusion pump (gastric stimulators, insulin pumps, and continuous glucose monitors are permitted): (1)
h. Positive pregnancy test: (1)
i. Were any of the items above (16a-h) checked:

Yes (* 1) No (2)

→ 19.

** If any of the above are checked, the Smart Pill® Capsule SHOULD NOT be administered*

17. Was the patient able to ingest the Smart Pill® Capsule:

Yes (1) No (2)

→ 19.

17a. Time patient ingested the Smart Pill®:

□□ : □□
(24-Hour clock)

18. Volume of water ingested with Smart Pill®: __ __ __ (mL)

E. Post prandial Symptom Scores

19. SYMPTOMS – Immediately, 0 minutes AFTER Smart Bar®/Smart Pill® ingestion

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

20. SYMPTOMS -- 15 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

21. SYMPTOMS -- 30 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

22. SYMPTOMS -- 45 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

23. SYMPTOMS -- 60 MINUTES AFTER finishing Smart Bar®

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

24. SYMPTOMS -- 90 MINUTES AFTER finishing Smart Bar® (at end of EGG)

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

At this time, give the last page of this form, "SmartPill Instruction Sheet" to the participant.

Participant must also complete the PAGI-SYM (GD form) as part of this test.
Use visit code s2 in item 5 of the GD form.

F. Calibration

25. Measure the length of the line below and enter the total length in millimeters: __ __ __ mm

G. EGG Data (Note: The EGG signal analysis must be performed on a minimum of 4 consecutive, artifact-free minutes per period)

26. What was the duration of the baseline 0-15 minute time period analyzed: __ __ (min)

27. What was the duration of the post satiety test 0-15 minute time period analyzed: __ __ (min)

28. What was the duration of the post satiety 16-30 minute time period analyzed: __ __ (min)

29. What was the duration of the post satiety 31-45 minute time period analyzed: __ __ (min)

30. What was the duration of the post satiety 46-60 minute time period analyzed: __ __ (min)

31. What was the duration of the post satiety 61-90 minute time period analyzed: __ __ (min)

32. Distribution of average power by frequency region (as % of power in the 0-15 cpm range) *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline (15):	**a.** _ _ _ . _ _%	**b.** _ _ _ . _ _%	**c**. _ _ _ . _ _%	**d.** _ _ _ . _ _%
0-15 post:	**e.** _ _ _ . _ _%	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _%	**h.** _ _ _ . _ _%
16-30 post:	**i.** _ _ _ . _ _%	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _%	**l.** _ _ _ . _ _%
31-45 post:	**m.** _ _ _ . _ _%	**n.** _ _ _ . _ _ %	**o.** _ _ _ . _ _%	**p.** _ _ _ . _ _%
46-60 post:	**q.** _ _ _ . _ _%	**r.** _ _ _ . _ _ %	**s.** _ _ _ . _ _%	**t.** _ _ _ . _ _%
61-90 post:	**u.** _ _ _ . _ _%	**v.** _ _ _ . _ _ %	**w.** _ _ _ . _ _%	**x.** _ _ _ . _ _%

33. Ratios of average powers (POSTprandial/PREprandial) by frequency range *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	Bradygastria (1- <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
0-15 post satiety:	**a.** _ _ _ . _ _	**b.** _ _ _ . _ _	**c.** _ _ _ . _ _	**d.** _ _ _ . _ _
16-30 post satiety:	**e.** _ _ _ . _ _	**f.** _ _ _ . _ _	**g** _ _ _ . _ _	**h.** _ _ _ . _ _
31-45 post satiety:	**i.** _ _ _ . _ _	**j.** _ _ _ . _ _	**k.** _ _ _ . _ _	**l.** _ _ _ . _ _
46-60 post satiety:	**m.** _ _ _ . _ _	**n.** _ _ _ . _ _	**o.** _ _ _ . _ _	**p.** _ _ _ . _ _
61-90 post satiety:	**q.** _ _ _ . _ _	**r.** _ _ _ . _ _	**s.** _ _ _ . _ _	**t.** _ _ _ . _ _

Data rounding rules for 34:

To round data, examine the digits following the last position required on the form:

· If the first digit following the last data position required for the response is less than 5, leave the digit in the last data position required for the response unchanged, e.g., if you need to round to __.__ __, then 1.4232 rounds to 1.42 and 1.443 rounds to 1.44

· If the first digit following the last data position required for the response is 5 or more, round up the digit in the last data position required for the response, e.g., if you need to round to __.__ __, then 1.4252 rounds to 1.43 and 4.756 rounds to 4.76

34. Distribution of average power by frequency range *(use data rounding rules above for 34. a.-x.)*:

Period (minutes)	Bradygastria (1- <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** _ . _ _ e+ _ _ _	**b.** _ . _ _ e+ _ _ _	**c**. _ . _ _ e+ _ _ _	**d.** _ . _ _e+_ _ _
0-15 post:	**e.** _ . _ _e+ _ _ _	**f.** _ . _ _ e+ _ _ _	**g.** _ . _ _ e+ _ _ _	**h.** _ . _ _e+ _ _ _
16-30 post:	**i.** _ . _ _e+ _ _ _	**j.** _ . _ _ e+ _ _ _	**k.** _ . _ _ e+ _ _ _	**l.** _ . _ _ e+ _ _ _
31-45 post:	**m.** _ . _ _e+ _ _ _	**n.** _ . _ _ e+ _ _ _	**o.** _ . _ _ e+ _ _ _	**p.** _ . _ _ e+ _ _ _
46-60 post:	**q.** _ . _ _e+ _ _ _	**r.** _ . _ _ e+ _ _ _	**s.** _ . _ _ e+ _ _ _	**t.** _ . _ _ e+ _ _ _
61-90 post:	**u.** _ . _ _e+ _ _ _	**v.** _ . _ _ e+ _ _ _	**w.** _ . _ _ e+ _ _ _	**x.** _ . _ _ e+ _ _ _

35. Average dominant frequency *(do not round the numbers; record as they appear on the report)*:

a. Baseline: _ _. _ _ cpm

b. 0-15 post: _ _. _ _ cpm

c. 16 -30 post: _ _. _ _ cpm

d. 31 -45 post: _ _. _ _ cpm

e. 46 -60 post: _ _. _ _ cpm

f. 61 -90 post: _ _. _ _ cpm

36. Percentage of time with the dominant EGG frequencies in the four frequency ranges:

Period (minutes)	**Bradygastria (1- <2.5 cpm)**	**Normal (2.5 - <3.8 cpm)**	**Tachygastria (3.8-10 cpm)**	**Duodenal (>10-15 cpm)**
Baseline:	**a.** _ _ _ %	**b.** _ _ _ %	**c**. _ _ _ %	**d.** _ _ _ %
0-15 post :	**e.** _ _ _ %	**f.** _ _ _ %	**g.** _ _ _ %	**h.** _ _ _ %
16-30 post:	**i.** _ _ _ %	**j.** _ _ _ %	**k.** _ _ _ %	**l.** _ _ _ %
31-45 post:	**m.** _ _ _ %	**n.** _ _ _ %	**o.** _ _ _ %	**p.** _ _ _ %
46-60 post:	**q.** _ _ _ %	**r.** _ _ _ %	**s.** _ _ _ %	**t.** _ _ _ %
61-90 post:	**u.** _ _ _ %	**v.** _ _ _ %	**w.** _ _ _ %	**x.** _ _ _ %

H. Administrative information

37. Study Physician PIN: __ __ __

38. Study Physician signature:

_____

39. Clinical Coordinator PIN: __ __ __

40. Clinical Coordinator signature:

_____

41. Date form reviewed:

__ __-__ __ __-__ __
day mon year

Attach a copy of the EGG report to this form.

SmartPill
The Measure of GI Health®

SmartPill Capsule

Important Patient Information and Instructions

Physician Contact Information:

1. For the Duration of the Test

- You must wear the data receiver on your body at all times for the duration of the test except when you bathe or shower. The data receiver can be worn on a lanyard around the neck or on a belt clip.

CAUTION

Do not bathe while wearing the data receiver – when you shower or bathe, you must remove the data receiver and place it as near to the shower or bathtub as possible.

CAUTION

Do not wear the lanyard when sleeping. Keep receiver within 3 feet while sleeping.

- No food or tobacco use for six (6) hours after starting the test. Food intake during the first six (6) hours after capsule ingestion will affect test results. You may have small quantities of water (up to 1/2 cup total) during the six (6) hours.
- Six (6) hours after capsule ingestion you may resume your normal diet and tobacco use. Your normal diet may be resumed at _____.
- Diabetic patients should monitor glucose levels and follow their personal treatment plan. If there is any uncertainty contact your doctor.
- Refrain from alcohol consumption until after the SmartPill capsule is passed.
- Refrain from using the medications listed below until after you return for your next GpR 2 study visit in 4-7 days:
  - Proton Pump Inhibitor Drugs (i.e. Protonix, Prilosec, Aciphex, Nexium, Dexilant)
  - H2 blockers (i.e. Ranitidine, Zantac, Pepcid)
  - Prokinetic agents (i.e. Reglan, Domperidone, Erythromycin)
  - Narcotic pain medications (i.e. Fentanyl, Morphine, Oxycodone)
  - Marinol, marijuana
  - Anticholinergics (i.e. Benadryl, Dramamine, Robinul, Advil PM, Bentyl, Dicyclomine, Levbid, Levsin, Hyoscyamine)
- Constipation medications (over-the-counter laxatives, isotonic polyethyleneglycol (PEG) electrolyte preparations (e.g. MiraLax), prescription laxatives (e.g. lubiprostone), bowel cathartics, anti-diarrhea medications, and any other medications that affect motility
- Complete any remaining questionnaires for GpR 2: Block Food Frequency Questionnaire, Block Energy Expenditure Survey, Nausea and Vomiting Questionnaire, Neuropathy Profile; Abdominal Pain Questionnaire, State-Trait Anxiety, etc.
- Avoid vigorous exercise such as sit-ups, abdominal crunches, and prolonged aerobic activity (greater than 15 minutes) until after the SmartPill capsule is passed.
- During the test, wait three (3) minutes in the lavatory before flushing the toilet after each bowel movement.
- The data receiver features an "EVENT" button. Press the EVENT button when you have a bowel movement and record the DATE and TIME of the EVENT in your diary. Your doctor may ask you to press the EVENT button for other events:

☐ Eating a meal	☐ Getting up in the morning
☐ Passing gas	☐ Going to bed at night
☐ Nausea	☐ Vigorous activity
☐ Cramping/pain	☐ Showering/bathing

2. Return fasting for your next Gastroparesis Registry 2 study visit.

- Bring the Data Receiver, diary, and any completed questionnaires to the follow-up appointment on:

_____ at _____.

Additional instructions from your physician:

_____

_____

_____

_____

WARNING

Do not have an MRI test while the SmartPill capsule is inside your body. Carry the warning card (below) at all times until your doctor confirms capsule exit.

MRI WARNING

I am currently undergoing a SmartPill test. SmartPill is an ingestible capsule device that restricts me from having an MRI.

If there are any questions, please contact my physician: _____

( ) –

CE 0473

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Molenstraat 15
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WL - EGG and Water Load Satiety Test

Purpose: To document symptoms and results of the water load satiety test and electrogastrogram in patients with gastroparesis.
When: Screening visit s and follow-up visit f048.
Administered by: Study Physician and Clinical Coordinator.
Respondent: Patient will respond to symptom evaluations on pages 2, 4-6.
Instructions: The Clinical Coordinator should complete section A. The Clinical Coordinator will use pages 2-6 to obtain patient's responses during the test procedure. The visual analog scales on pages 2, 4, 5, and 6 are 100 mm in length and should be measured from left to right with a metric (SI) ruler. Enter the value closest to the patient's vertical line in millimeters (0-100 mm) in items 10, 15, 16, and 17. **Choose only whole numbers. Do not select more than 15 minutes for the baseline period. Do not select more than 10 minutes for any post water-load satiety recording period.** Using the EGG report, complete section F. The Study Physician and Clinical Coordinator should complete Section G. Attach a copy of the EGG report to this form. Save the raw digital EGG data to a USB flash drive.

A. Clinic, visit, and patient identification

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: w l 1

7. Study: GpR 2 5

8. Has the patient fasted since midnight:

Yes	No
(1)	(* 2) Stop

* *Patient must be fasting; test must be rescheduled.*

9. Is the patient's blood glucose level <270 mg/dL:

Yes	(1)
No	(* 2) Stop
NA/not diabetic	(3)

** Glucose must be less than 270 mg/dL; test must be rescheduled.*

B. Baseline Symptom Scores

10. BASELINE SYMPTOMS - - at the START of the 15 minute baseline EGG recording

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

NOT FULL AT ALL — COMPLETELY FULL

__ __ __ mm

b. HUNGER

NONE — EXTREME

__ __ __ mm

c. NAUSEA

NONE — SEVERE

__ __ __ mm

d. BLOATING

NONE — SEVERE

__ __ __ mm

e. ABDOMINAL PAIN

NONE — SEVERE

__ __ __ mm

C. NON-CALORIC WATER LOAD SATIETY TEST VOLUME

Instructions to patients for the Water Load Satiety Test are as follows:

"You will be given a cup of bottled spring water to drink for 5 minutes until you feel completely full. You will have up to 5 minutes to drink the cup of water. You may use all of this time, if needed. After you finish, we will ask about your feeling of fullness on a five-point scale, that is 0, 1, 2, 3, 4, 5 where 0 is not full at all and 5 is completely full. You will stop drinking when you become completely full from the water. This is not a test to see how much you can drink, but simply to have you drink until you feel completely full."

Subject drinks spring water, refrigerated at 4 degrees C, from a 16 ounce cup over a 5 minute period or until he/she feels completely full.

11. Time Non-Caloric Water Load Satiety Test Started: __ __ : __ __
(24-hour)

12. Time Satiety Test Ended: __ __ : __ __
(24-hour)

13. Please rate your feeling of fullness on a scale of 0-5 *(0 is not full; 5 is completely full)*: __
(0-5)

14. Total Volume of Water Consumed: __ __ __ __
mL

D. Post Water Load Satiety Symptom Scores

15. SYMPTOMS -- 10 minutes AFTER finishing water

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

16. SYMPTOMS -- 20 MINUTES AFTER finishing water

__ __ __ __ __ __ __

□□ : □□

(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

__ __ __ mm

NOT FULL AT ALL — COMPLETELY FULL

b. HUNGER

__ __ __ mm

NONE — EXTREME

c. NAUSEA

__ __ __ mm

NONE — SEVERE

d. BLOATING

__ __ __ mm

NONE — SEVERE

e. ABDOMINAL PAIN

__ __ __ mm

NONE — SEVERE

17. SYMPTOMS -- 30 MINUTES AFTER finishing water (At end of EGG)

□□ : □□
(24-Hour clock)

Mark each symptom line with a vertical line where you believe each of the following words best describes how you currently feel (PLEASE make ONLY ONE VERTICAL LINE for each symptom).

a. STOMACH FULLNESS

NOT FULL AT ALL — COMPLETELY FULL

__ __ __ mm

b. HUNGER

NONE — EXTREME

__ __ __ mm

c. NAUSEA

NONE — SEVERE

__ __ __ mm

d. BLOATING

NONE — SEVERE

__ __ __ mm

e. ABDOMINAL PAIN

NONE — SEVERE

__ __ __ mm

E. Calibration

18. Measure the length of the line below and enter the total length in millimeters: __ __ __ mm

F. EGG data: *(Note: The EGG signal analysis must be performed on a minimum of 6 consecutive, artifact-free minutes per period.)*

19. What was the duration of the baseline 0-15 minute time period analyzed: __ __ *(min)*

20. What was the duration of the post satiety test 0-10 minute time period analyzed: __ __ *(min)*

21. What was the duration of the post satiety test 11-20 minute time period analyzed: __ __ *(min)*

22. What was the duration of the post satiety test 21-30 minute time period analyzed: __ __ *(min)*

23. Distribution of average power by frequency region (as % of power in the 0-15 cpm range) *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** _ _ _ . _ _ %	**b.** _ _ _ . _ _ %	**c.** _ _ _ . _ _ %	**d.** _ _ _ . _ _ %
0-10 post satiety:	**e.** _ _ _ . _ _ %	**f.** _ _ _ . _ _ %	**g.** _ _ _ . _ _ %	**h.** _ _ _ . _ _ %
11-20 post satiety:	**i.** _ _ _ . _ _ %	**j.** _ _ _ . _ _ %	**k.** _ _ _ . _ _ %	**l.** _ _ _ . _ _ %
21-30 post satiety:	**m.** _ _ _ . _ _ %	**n.** _ _ _ . _ _ %	**o.** _ _ _ . _ _ %	**p.** _ _ _ . _ _ %

24. Ratios of average power (POSTsatiety/PREsatiety) by frequency range *(do not round the numbers; record as they appear on the report)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
0-10 post satiety:	**a.** _ _ _ . _ _	**b.** _ _ _ . _ _	**c.** _ _ _ . _ _	**d.** _ _ _ . _ _
11-20 post satiety:	**e.** _ _ _ . _ _	**f.** _ _ _ . _ _	**g.** _ _ _ . _ _	**h.** _ _ _ . _ _
21-30 post satiety:	**i.** _ _ _ . _ _	**j.** _ _ _ . _ _	**k.** _ _ _ . _ _	**l.** _ _ _ . _ _

Data rounding rules for 25:

To round data, examine the digits following the last position required on the form:

· If the first digit following the last data position required for the response is less than 5, leave the digit in the last data position required for the response unchanged, e.g., if you need to round to __.__ __, then 1.4232 rounds to 1.42 and 1.443 rounds to 1.44

· If the first digit following the last data position required for the response is 5 or more, round up the digit in the last data position required for the response, e.g., if you need to round to __.__ __, then 1.4252 rounds to 1.43 and 4.756 rounds to 4.76

25. Distribution of average power by frequency range *(follow data rounding rules for 25. a.-p.)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** __.__ __e+__ __ __	**b.** __.__ __e+__ __ __	**c.** __.__ __e+__ __ __	**d.** __.__ __e+__ __ __
0-10 post satiety:	**e.** __.__ __e+__ __ __	**f.** __.__ __e+__ __ __	**g.** __.__ __e+__ __ __	**h.** __.__ __e+__ __ __
11-20 post satiety:	**i.** __.__ __e+__ __ __	**j.** __.__ __e+__ __ __	**k.** __.__ __e+__ __ __	**l.** __.__ __e+__ __ __
21-30 post satiety:	**m.** __.__ __e+__ __ __	**n.** __.__ __e+__ __ __	**o.** __.__ __e+__ __ __	**p.** __.__ __e+__ __ __

26. Average dominant frequency *(do not round; record the numbers as they appear on the report)*:

a. Baseline: __ __ . __ __ cpm

b. 0-10 post satiety: __ __ . __ __ cpm

c. 11-20 post satiety: __ __ . __ __ cpm

d. 21-30 post satiety: __ __ . __ __ cpm

27. Percentage of time with the dominant EGG frequencies in the four frequency ranges *(do not round; record the numbers as they appear on the report)*:

Period (minutes)	Bradygastria (1 - <2.5 cpm)	Normal (2.5 - <3.8 cpm)	Tachygastria (3.8-10 cpm)	Duodenal (>10-15 cpm)
Baseline:	**a.** __ __ __ %	**b.** __ __ __ %	**c.** __ __ __ %	**d.** __ __ __ %
0-10 post satiety:	**e.** __ __ __ %	**f.** __ __ __ %	**g.** __ __ __ %	**h.** __ __ __ %
11-20 post satiety:	**i.** __ __ __ %	**j.** __ __ __ %	**k.** __ __ __ %	**l.** __ __ __ %
21-30 post satiety:	**m.** __ __ __ %	**n.** __ __ __ %	**o.** __ __ __ %	**p.** __ __ __ %

G. Administrative information

28. Study Physician PIN: __ __ __

29. Study Physician signature:

_____

30. Clinical Coordinator PIN: __ __ __

31. Clinical Coordinator signature:

_____

32. Date form reviewed:

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

Attach a copy of the EGG report to this form.

Gastroparesis Registry 2

WM - Wireless Motility Capsule Report Form

Purpose: To document results of the wireless motility capsule (WMC) test in patients with gastroparesis.

When: Screening visit.

By whom: Study Physician and Clinical Coordinator.

Instructions: The Clinic Coordinator should complete section A. The Study Physician and/or Clinical Coordinator should use the SmartPill® test report and the patient diary to complete sections B and C. The Study Physician and Clinical Coordinator should complete Section D. Attach a copy of the SmartPill® test report to this form. **Save the raw SmartPill® data to the USB flash drive.**

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

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

5. Visit code: s ____ ____ ____

6. Form & revision: w m 1

7. Study: GpR 2 5

B. Quality of Study

8. Did the patient sucessfully swallow and retain the SmartPill® wireless motility capsule for at least 5 hours:

Yes (1) No (2)

20.

9. Duration of total recording time *(i.e., how long the receiver was recording data from capsule ingestion to return of SmartPill® recorder):*

____ ____ ____:____ ____
hours minute

10. Did the capsule empty from the acidic stomach into the alkaline small intestine:

Yes (1)
No (2)
Unsure (3)

11. Is the ileocolonic junction (ICJ) identifiable on the pH tracing:

Yes (1)
No (2)
Unsure (3)

12. Is there confirmation of the capsule exiting the body:

Yes (1)
No (2)
14.
Unsure (3)
14.

13. Capsule excretion confirmed by *(check all that apply):*

a. Observation of capsule in stool: (1)
b. Temperature drop: (1)
c. BM consistent with data dropping: (1)
d. Other, *(specify):* (1)

_____
specify

C. Test statistics

14. Transit Times (hrs:min) *(calculated by physician):*

a. Gastric emptying time (GET):

____ ____ ____:____ ____
hours minute

b. Small bowel transit time (SBTT):

____ ____ ____:____ ____
hours minute

c. Colon transit time (CTT):

____ ____ ____:____ ____
hours minute

d. Combined small/large bowel transit time (SLBTT):

____ ____ ____:____ ____
hours minute

e. Whole gut transit time (WGTT):

____ ____ ____:____ ____
hours minute

15. Gastric pH:

a. High pH: ___ ___ • ___

b. Low pH: ___ ___ • ___

16. Range Annotations 30 minutes **post** gastric emptying (Small Intestinal pressure):

a. Start:

___ ___:___ ___
hours minute

b. End:

___ ___:___ ___
hours minute

c. Contractions/min:

___ ___ • ___ ___

d. 30 minutes post Mean Amplitude:

___ ___ ___ • ___ ___
mmHg

e. 30 minutes post Motility Index:

___ ___ ___ • ___ ___
mmHg

17. Range Annotations 30 minutes **prior** to gastric emptying (antral pressure):

a. Start:

___ ___:___ ___
hour minute

b. End:

___ ___:___ ___
hour minute

c. Contractions/min:

___ ___ • ___ ___

d. 30 minutes prior Mean Amplitude:

___ ___ ___ • ___ ___
mmHg

e. 30 minutes prior Motility Index:

___ ___ ___ • ___ ___
mmHg

18. Number of bowel movements during the WMC recording time of WGTT *(from capsule ingestion to capsule excretion; data from patient diary and review with patient):*

___ ___

19. Interpretation of wireless motility capsule test:

_____
_____
_____
_____
_____

20. Comments on the wireless motility capsule test:

_____
_____
_____
_____
_____

D. Administrative information

21. Study Physician PIN: ___ ___ ___

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ___ ___ ___

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

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

Attach a copy of the SmartPill® Test Report to this form.

Gastroparesis Registry 2

WM - Wireless Motility Capsule Report Form

Purpose: To document results of the wireless motility capsule (WMC) test in patients with gastroparesis.

When: Complete this form at the screening visit when the WMC receiver is returned. If the capsule exit is not confirmed, complete the WR - Wireless Motility Capsule Retention Form.

By whom: Study Physician and Clinical Coordinator.

Instructions: The Clinic Coordinator should complete section A. The Study Physician and/or Clinical Coordinator should use the SmartPill® test report and the patient diary to complete sections B and C at the time the receiver is returned. The Study Physician and Clinical Coordinator should complete Section D. Attach a copy of the SmartPill® test report to this form. **Save the raw SmartPill® data to the USB flash drive.**

A. Center, patient and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

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

5. Visit code: s ____ ____ ____

6. Form & revision: w m 2

7. Study: GpR 2 5

B. Quality of Study

8. Did the patient sucessfully swallow and retain the SmartPill® wireless motility capsule for at least 5 hours:

Yes (1) No (2)

20. ____

9. Duration of total recording time *(i.e., how long the receiver was recording data from capsule ingestion to return of SmartPill® recorder):*

____ ____ ____:____ ____
hours minute

10. Did the capsule empty from the acidic stomach into the alkaline small intestine:

Yes (1)
No (2)
Unsure (3)

11. Is the ileocolonic junction (ICJ) identifiable on the pH tracing:

Yes (1)
No (2)
Unsure (3)

12. Is there confirmation of the capsule exiting the body at the time the receiver is returned:

Yes, exit confirmed at the time of receiver return (1)
No, exit not confirmed at the time of receiver return (*2)

** Complete the WR form*

13. Capsule excretion confirmed by *(check all that apply):*

a. Observation of capsule in stool: (1)
b. Temperature drop: (1)
c. BM consistent with data dropping: (1)
d. Abdominal X-ray: (*1)

** Complete the AE form if an AXR was performed at the visit when the receiver was returned*

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

_____
specify

C. Test statistics

14. Transit Times (hrs:min) *(calculated by physician):*

a. Gastric emptying time (GET):
____ ____ ____:____ ____
hours minute

b. Small bowel transit time (SBTT):
____ ____ ____:____ ____
hours minute

c. Colon transit time (CTT):
____ ____ ____:____ ____
hours minute

d. Combined small/large bowel transit time (SLBTT):
____ ____ ____:____ ____
hours minute

e. Whole gut transit time (WGTT):
____ ____ ____:____ ____
hours minute

15. Gastric pH:

a. High pH: ___ ___ • ___

b. Low pH: ___ ___ • ___

16. Range Annotations 30 minutes **post** gastric emptying (Small Intestinal pressure):

a. Start:

___ ___:___ ___
hours minute

b. End:

___ ___:___ ___
hours minute

c. Contractions/min:

___ ___ • ___ ___

d. 30 minutes post Mean Amplitude:

___ ___ ___ • ___ ___
mmHg

e. 30 minutes post Motility Index:

___ ___ ___ • ___ ___
mmHg

17. Range Annotations 30 minutes **prior** to gastric emptying (antral pressure):

a. Start:

___ ___:___ ___
hour minute

b. End:

___ ___:___ ___
hour minute

c. Contractions/min:

___ ___ • ___ ___

d. 30 minutes prior Mean Amplitude:

___ ___ ___ • ___ ___
mmHg

e. 30 minutes prior Motility Index:

___ ___ ___ • ___ ___
mmHg

18. Number of bowel movements during the WMC recording time of WGTT *(from capsule ingestion to capsule excretion; data from patient diary and review with patient):*

___ ___

19. Interpretation of wireless motility capsule test:

_____

_____

_____

_____

_____

20. Comments on the wireless motility capsule test:

_____

_____

_____

_____

_____

D. Administrative information

21. Study Physician PIN: ___ ___ ___

22. Study Physician signature:

_____

23. Clinical Coordinator PIN: ___ ___ ___

24. Clinical Coordinator signature:

_____

25. Date form reviewed:

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

Attach a copy of the SmartPill® Test Report to this form.

Keyed: ( )

Gastroparesis Registry 2 WR - Wireless Motility Capsule Retention Form

Purpose: To document retention of the wireless motility capsule (WMC) in GpR 2 participants.
When: Complete within 7-10 days following the screening visit(s) after the wireless motility capsule receiver was returned and capsule exit was not confirmed; use visit code "n". If more than one event is reported, use visit code "n1" for second event, "n2" for third event, etc.
Administered by: Study Physician and Clinical Coordinator.
Instructions: The Clinic Coordinator should complete section A. The Study Physician and/or Clinical Coordinator should complete sections B and C to document the capsule retention, follow-up care, and exit of capsule (if applicable).

A. Center, patient, and visit identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Date of visit:

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

5. Visit code: ____ ____ ____ ____

6. Form & revision: w r 1

7. Study: GpR 2 5

B. Capsule retention

8. Has there been confirmation of the capsule exiting the body after the visit when the receiver was returned:

Capsule exit was not confirmed at the time of receiver return, but capsule exit later confirmed (1)

Capsule exit was not confirmed at the time of receiver return and capsule exit has not been confirmed (2)

10.

9. Capsule exit was confirmed by *(check only one):*

Observation of capsule in stool/toilet: (1)

Abdominal X-ray *(Complete the AE form if an AXR was performed):* (*2)

Capsule exit confirmed by another procedure *(CT, abdominal ultrasound, fluoroscopy) (complete the AE form):* (*3)

Capsule required a procedure to retrieve: (*4)

Other *(specify):* (5)

_____

** Complete the AE form if a procedure was performed to confirm exit (AXR, CT, ultrasound, fluoroscopy, etc.).*

11.

C. Follow-up care for retained capsule

10. Capsule exit was not confirmed and the follow-up care of the participant will be *(check only one):*

Perform an abdominal X-ray (AXR) approximately every 3 weeks until capsule is eliminated *(complete the WR1 form again when exit is confirmed):* (*1)

Capsule was in the colon and no abdominal X-ray will be performed (2)

Patient is asymptomatic and physician does not recommend AXR (3)

Patient declines an abdominal x-ray and has been counseled of potential risks (4)

Capsule required a procedure to retrieve (*5)

Other *(specify):* (6)

_____

** Complete the AE form.*

D. Administrative information

11. Study Physician PIN: ____ ____ ____

12. Study Physician signature:

_____

13. Clinical Coordinator PIN: ____ ____ ____

14. Clinical Coordinator signature:

_____

15. Date form reviewed:

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