

GpCRC

*Gastroparesis
Clinical Research Consortium*

Gastroparesis Registry
Standard Operating Procedures
Part I: Clinical Center Operations

4 November 2008

GpR SOP Part I: Clinical Center Operations

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1. Design overview

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1.1. Design synopsis

Objectives

- To establish a registry of patients with gastroparesis for the study of the epidemiology, etiology, and degree of morbidity associated with gastroparesis.
- To prospectively and systematically follow a well-characterized cohort to define the natural history and clinical course of gastroparesis.
- To provide a reliable resource for rapid recruitment of well-characterized patients with gastroparesis for therapeutic clinical trials, pathophysiological, molecular, histopathologic, or other ancillary studies. These subsequent clinical trials or other ancillary studies will each be conducted under separate study protocols with separate consent processes.

Type of study

- Observational

Population

- Patients at least 18 years of age
- Gastroparesis patients with delayed gastric emptying
- Patients without nausea, but with other symptoms suggestive of gastroparesis and with delayed gastric emptying
- Patients with symptomatic nausea and vomiting, but without delayed gastric emptying

Inclusion criteria

- 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, post-prandial fullness
- Completion of a 4-hour scintigraphic low fat Egg Beaters gastric emptying study
 - Patients with either or both abnormal 2 hour (>60% retention) and 4 hour (>10% retention) gastric emptying will be enrolled and classified as definite gastroparesis
 - Patients with normal gastric emptying, but with symptoms of gastroparesis may be enrolled and classified as possible gastroparesis
- Age at least 18 years at initial screening visit
- Ability and willingness to participate in follow-up

Exclusion criteria

- Inability to comply with or complete the gastric emptying test by scintigraphy
- Presence of other conditions that could explain the patient's symptoms:
 - Pyloric or intestinal obstruction

1.1. Design synopsis

- Active inflammatory bowel disease
- Eosinophilic gastroenteritis
- Neurological conditions such as increased intracranial pressure, space occupying or inflammatory/infectious lesions
- Acute liver failure
- Advanced liver disease (Child's B or C; a CPT score of 7 or greater)
- Acute renal failure
- Untreated chronic renal failure (serum creatinine >3 mg/dL)
- Total or subtotal gastric resection (patients with prior fundoplication or postvagotomy gastroparesis after pyloroplasty or antrectomy with Billroth I, Billroth II, or Roux-en-Y gastrojejunostomy will be eligible for enrollment)
- Any other plausible structural or metabolic cause
- Any other condition, which in the opinion of the investigator would interfere with study requirements
- Inability to obtain informed consent

Recruitment

- To Gastroparesis Registry (GpR) goal of 500 enrolled patients (100/clinical center)
- 36 month period
- Recruitment rate of 2.8 patients/clinical center/month

Duration of followup

- 48-192 weeks (1-4 years)

Visit schedule

- Screening/entry into Gastroparesis Registry: enrollment must occur within 16 weeks of initiation of screening
- Follow-up visits at 16 weeks, 32 weeks, 48 weeks, 64 weeks, 80 weeks, 96 weeks, 112 weeks, 128 weeks, 144 weeks, 160 weeks, 176 weeks, and 192 weeks

Outcome measures

- Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM)
- Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)
- Scintigraphic gastric emptying test
- HbA1c and glucose levels
- Body mass index
- Health related quality of life (SF-36)

1.1. Design synopsis

- Brief pain inventory
- Nutritional intake
- Investigator Derived Independent Outcome Measure Scores (IDIOMS)
- Management of gastroparesis
- Beck Depression Inventory
- State Trait Anxiety Inventory
- Rome III questionnaires
- Survival at the end of study period

Sample size

- Separately justified for each hypothesis
 - Specification of primary outcome measure for hypothesis
 - Type I error ≤ 0.05 and power ≥ 0.80
 - Specification of primary comparison groups
 - Specification of minimum clinically meaningful effect size for the primary outcome
 - Specification of method for handling missing data
 - No adjustments for multiplicity of comparisons
-

1.2. Data collection schedule

	Screening visits	Follow-up visits:											
		Weeks from enrollment											
	screen/enrollment	16	32	48	64	80	96	112	128	144	160	176	192
Consent, HIPAA authorization	X
Baseline medical history	X
Follow-up medical history	.	X	X	X	X	X	X	X	X	X	X	X	X
Interim event form as needed (A)*	.	A	A	A	A	A	A	A	A	A	A	A	A
PAGI-SYM questionnaire	X	X	X	X	X	X	X	X	X	X	X	X	X
PAGI-QOL questionnaire	X	X	X	X	X	X	X	X	X	X	X	X	X
Rome III battery	X	.	.	X	.	.	X	.	.	X	.	.	X
Brief Pain Inventory	X	X	X	X	X	X	X	X	X	X	X	X	X
IDIOMS	X	X	X	X	X	X	X	X	X	X	X	X	X
Gastric emptying scintigraphy	X
Physical examination	X	X	X	X	X	X	X	X	X	X	X	X	X
Upper gastrointestinal endoscopy	X
Eligibility confirmation	X
Beck Depression Inventory	X	.	.	X	.	.	X	.	.	X	.	.	X
STAI: Self evaluation questionnaire	X	.	.	X	.	.	X	.	.	X	.	.	X
Block Food Questionnaire	X	.	.	X	.	.	X	.	.	X	.	.	X
SF-36 quality of life	X	.	.	X	.	.	X	.	.	X	.	.	X
Hematology*	X	A	A	A	A	A	A	A	A	A	A	A	A
Liver panel*	X	A	A	A	A	A	A	A	A	A	A	A	A
Clinical chemistry*	X	A	A	A	A	A	A	A	A	A	A	A	A
HbA1c†	X	X	X	X	X	X	X	X	X	X	X	X	X
ANA, Scl-70, CRP, SPEP, Sed rate	X	.	.	A	.	.	A	.	.	A	.	.	A
Serum, plasma banking	X	.	.	X	.	.	X	.	.	X	.	.	X
DNA for banking	X

Hematology panel includes hemoglobin, hematocrit, white blood cell count (WBC), platelet count, prothrombin time (PT), partial thromboplastin time (PTT)

Liver panel includes total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase

Clinical chemistry panel includes creatinine, total protein and albumin, sodium, potassium, chloride, bicarbonate, calcium, BUN, glucose

* A = as needed

†HbA1c is required at each follow-up visit for diabetic patients

1.3. Whole blood draw schedule: mL of blood to be drawn at screening and followup visits

Procedure	Study visits (wk)					Total
	screening/ enrollment	48	96	144	192	
Serology (ANA, Scl-70, CRP, SPEP, Sed rate)	10	10
Hematology	5	5
Clinical chemistry	5	5
Liver panel	5	5
HbA1c†	5	5
Fasting* plasma, serum banking	20	20	20	20	20	100
DNA banking	20	20
Total	70	20	20	20	20	150

Hematology panel includes hemoglobin, hematocrit, white blood cell count (WBC), platelet count, prothrombin time (PT), partial thromboplastin time (PTT)

Liver panel includes total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase

Clinical chemistry panel includes creatinine, total protein and albumin, sodium, potassium, chloride, bicarbonate, calcium, BUN, glucose

* Fasting is defined as nothing by mouth except water in the 8 hours prior to blood draw. Fasting visits need to be scheduled for early morning and the patient must attend the visit after an overnight fast of at least 8 hours.

†HbA1c panel will be obtained at every follow-up visit for diabetic patients only

1.4. Study population composition

- 500 patients age 18 or older with:
 - Gastroparesis with delayed gastric emptying
 - Symptoms suggestive of gastroparesis with delayed gastric emptying but without nausea
 - Symptomatic nausea and vomiting without delayed gastric emptying (~20%)
 - ~100 patients per clinical center
 - 30 - 40% diabetic
-

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2. Eligibility and enrollment

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2.1. Inclusion and exclusion criteria

Inclusion criteria

- 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, postprandial fullness,
- Completion of a 4-hour scintigraphic low fat Egg Beaters gastric emptying study
 - Patients with either or both abnormal 2 hour (>60% retention) and 4 hour (>10% retention) gastric emptying will be enrolled and classified as definite gastroparesis (Gp)
 - Patients with normal gastric emptying, but with symptoms of gastroparesis may be enrolled and classified as possible gastroparesis or gastroparesis-like with normal gastric emptying (GLNGE)
- Age at least 18 years at initial screening visit
- Ability and willingness to participate in follow-up

Exclusion criteria

- Inability to comply with or complete the gastric emptying scintigraphy
- Presence of other conditions that could explain the patient's symptoms:
 - Pyloric or intestinal obstruction
 - Active inflammatory bowel disease
 - Eosinophilic gastroenteritis
 - Neurological conditions such as increased intracranial pressure, space occupying or inflammatory/infectious lesions
 - Acute liver failure
 - Advanced liver disease (Child's B or C; a CPT score of 7 or greater)
 - Acute renal failure
 - Untreated chronic renal failure (serum creatinine >3 mg/dL)
- Total or subtotal gastric resection (patients with prior fundoplication or postvagotomy gastroparesis after pyloroplasty or antrectomy with Billroth I, Billroth II, or Roux-en-Y gastrojejunostomy will be eligible for enrollment)
- Any other plausible structural or metabolic cause
- Any other condition, which in the opinion of the investigator would interfere with study requirements
- Inability to obtain informed consent

2.1. Inclusion and exclusion criteria

Clinical centers must be certified by the Data Coordinating Center to start enrollment in the Gastroparesis Registry. Prior to implementation of this protocol, the principal investigator must have the protocol and consent form approved by the Institutional Review Board for Human Research (IRB) at his/her institution. Once a candidate for Gastroparesis Registry has been identified, details will be carefully discussed with the patient. The patient will be asked to read and sign the consent form that was approved by the IRB. There will be a separate consent for the collection, storage, and use of DNA for genetic research.

2.2. Calculation of Child-Pugh-Turcotte score

Child-Pugh-Turcotte (CPT) score for severity of liver disease will be calculated as follows:

	Points
1. Serum albumin (g/dL; recorded on the LR form)	
greater than 3.5	1
2.8 – 3.5	2
less than 2.8	3
2. Serum total bilirubin (mg/dL; recorded on the LR form)	
less than 2.0	1
2.0 – 3.0	2
greater than 3.0	3
3. Prothrombin time (INR; recorded on the LR form)	
less than 1.7	1
1.7 – 2.3	2
greater than 2.3	3
4. Ascites: use all available information from all sources and best medical judgement	
None	1
Mild, easily managed	2
Severe, refractory	3
5. Encephalopathy: use all available information from all sources and best medical judgement	
None	1
Mild, easily managed	2
Severe, refractory	3
Child's stage A: 5-6 points	
Child's stage B: 7-9 points	
Child's stage C: 10-15 points	

2.3. Rome III Diagnostic Questionnaire scoring algorithm

For Functional Dyspepsia (FD) Module

B1. Functional Dyspepsia

Diagnostic criteria*

Must include:

1. One or more of:
 - a. Bothersome postprandial fullness
Uncomfortably full after regular sized meal, more than 1 day/week (question 13>4)
Onset more than 6 months ago (question 14=1)
 - b. Early satiation
Unable to finish regular sized meal, more than 1 day/week (question 15 >4)
Onset more than 6 months ago. Yes. (question 16=1)
 - c. Epigastric pain
Pain or burning in middle of abdomen, at least 1 day/week (question 17>3)
Onset more than 6 months ago. Yes. (question 18=1)
 - d. Epigastric burning
(This criterion is incorporated in the same question as epigastric pain)

AND

1. No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms
No question.

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
Yes. (question 18=1)

2.3. Rome III scoring algorithm

B1a: Postprandial Distress Syndrome**Diagnostic criteria***

Must include **one or both** of the following:

1. Bothersome postprandial fullness, occurring after ordinary-sized meals, at least several times per week
Uncomfortably full after regular-sized meal, more than 1 day/week (question 13>4)
2. Early satiation that prevents finishing a regular meal, at least several times per week
Unable to finish regular-sized meal more than 1 day/week (question 15>4)

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Requires a "Yes" to both. (question 14=1) & (question 16=1)

B1b: Epigastric Pain Syndrome**Diagnostic criteria***

Must include **all** of the following:

1. Pain or burning localized to the epigastrium, of at least moderate severity at least once per week
Pain or burning in middle of abdomen, at least 1 day/week (question 17>3)
Pain is at least moderate severity (question 20>2)
2. The pain is intermittent
Pain or burning often disappears completely in the same day (question 19>1)
3. Not generalized or localized to other abdominal or chest regions
Chest pain occurs once a month or less often (question 11 <3)
Heartburn occurs once a month or less often (question 12 <3)
4. Not relieved by defecation or passage of flatus
Never or rarely gets better after defecation (question 22=0)
5. Not fulfilling criteria for gallbladder and sphincter of Oddi disorders
6. Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
Yes. (question 18 =1)

2.3. Rome III scoring algorithm

B2. Belching Disorders**B2a: Aerophagia****Diagnostic criteria***

Must include **all** of the following:

1. Troublesome repetitive belching at least several times a week
Bothersome belching more than 1 day a week (question 42>4)
2. Air swallowing that is objectively observed or measured
No question

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 43=1)

B2b. Unspecified Excessive Belching**Diagnostic criteria***

Must include **all** of the following:

1. Troublesome repetitive belching at least several times a week
Bothersome belching more than 1 day a week (question 42 > 4)
2. No objective evidence that excessive air swallowing underlies the symptom

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

Yes. (question 43=1)

B3a: Chronic Idiopathic Nausea**Diagnostic criteria***

Must include **all** of the following:

1. Bothersome nausea, occurring at least several times per week
Nausea more than once a week (question 31>4)
2. Not usually associated with vomiting
Vomiting less than one day a week (question 33<4)

2.3. Rome III scoring algorithm

3. Absence of abnormalities at upper endoscopy or metabolic disease that explains the nausea

No question.

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 32=1)

B3b: Functional vomiting**Diagnostic criteria***

Must include **all** of the following:

1. On average one or more episodes of vomiting per week
Vomiting occurs at least once a week (question 33>3)
2. Absence of criteria for an eating disorder, rumination, or major psychiatric disease according by DSM-IV
Patient does not meet criteria for Rumination Disorder
No questions for eating disorder or major psychiatric disease.
3. Absence of self-induced induced vomiting and chronic cannabinoid use and absence of abnormalities in the central nervous system or metabolic diseases to explain the recurrent vomiting
Never or rarely make yourself vomit (question 35=0)

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 34=1)

B3c: Cyclic Vomiting Syndrome**Diagnostic criteria**

Must include **all** of the following:

1. Stereotypical episodes of vomiting regarding onset (acute) and duration (less than one week)
Vomiting occurs more often than 'never or rarely' (question 33>0)

2.3. Rome III scoring algorithm

2. Three or more discrete episodes in the prior year
At least 3 episodes during the year. Yes. (question 37=1)
3. Absence of nausea and vomiting between episodes
Occurred in separate episodes and then stopped at least sometimes (question 36>0)

B4: Rumination Syndrome in Adults**Diagnostic criteria***

Must include **all** of the following:

1. Persistent or recurrent regurgitation of recently ingested food into the mouth with subsequent spitting or remastication and swallowing
Bring up food at least 1 day/week (question 38>3)
Hold food in mouth before spitting or swallowing often (question 40>1)
2. Regurgitation is not preceded by retching
Was bringing up food preceded by retching? No. (question 41=0)

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
Yes. (question 39=1)

C. Functional Bowel Disorders**C1. Irritable Bowel Syndrome****Diagnostic Criterion***

Recurrent abdominal pain or discomfort** at least 3 days/month in last 3 months associated with *two or more* of criteria #1-#3 below.

Pain or discomfort at least 2 to 3 days/month (question 44 > 2)

For women, does pain occur only during menstrual bleeding?

(question 46=0 or 2)

1. Improvement with defecation
Pain or discomfort gets better after defecation at least sometimes
(question 49>0)

2.3. Rome III scoring algorithm

2. Onset associated with a change in frequency of stool
Onset of pain or discomfort associated with more stools at least sometimes (question 50>0), OR
3. Onset associated with a change in form (appearance) of stool
Onset of pain or discomfort associated with looser stools, at least sometimes (question 52>0), OR
Onset of pain or discomfort associated with harder stools, at least sometimes (question 53>0)

*Criterion fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 48=1)

**“Discomfort” means an uncomfortable sensation not described as pain.

In pathophysiology research and clinical trials, a pain/discomfort frequency of at least 2 days a week during screening evaluation is recommended for subject eligibility.

D. Functional abdominal pain syndrome

Diagnostic criteria*

Must include **all** of the following:

1. Continuous or nearly continuous abdominal pain
Pain or discomfort occurs every day (question 44=6)
Subject experiences only pain, not discomfort (question 45=1)
2. No or only occasional relationship of pain with physiological events (e.g., eating, defecation or menses)
Pain is affected by eating sometimes or less often (question 54<2)
Pain stops or lessens with defecation sometimes or less often (question 49<2)
Pain onset is associated with more frequent stools sometimes or less often (question 47<2)
Pain onset is associated with fewer stools sometimes or less often (question 51<2)
Pain onset is associated with looser stools (question 52<2)
Pain onset is associated with harder stools (question 53<2)

2.3. Rome III scoring algorithm

Pain or burning is associated with a change in stool consistency never, rarely, or sometimes (question 50<2)

Pain or burning is associated with a change in stool frequency never, rarely, or sometimes (question 48<2)

For women pain is not limited to menstrual bleeding, or question is not applicable (question 46=0 or 2)

3. Some loss of daily functioning

Pain limits activity at least some of the time (question 47>0)

4. The pain is not feigned (e.g., malingering)

No question

5. Insufficient symptoms to meet criteria for another functional gastrointestinal disorder that would explain the pain

Epigastric pain syndrome criteria not met, &

IBS criteria not met, &

Anorectal pain criteria not met

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 48=1)

E. Functional Gallbladder and Sphincter of Oddi Disorders (for exclusion)

Diagnostic criteria

Must include episodes of pain located in the epigastrium and/or right upper quadrant

Steady pain which may occur less than once per month (question 24>0)

AND all of the following:

1. Episodes lasting 30 minutes or longer

At least often (question 25>1)

2. Recurrent symptoms occurring at different intervals (not daily)

At least often (question 27>1)

 2.3. Rome III scoring algorithm

3. The pain builds up to a steady level
At least often (question 26>1)
4. The pain is moderate to severe enough to interrupt the patient's daily activities or lead to an emergency department visit
At least often (question 28>1)
5. The pain is not relieved by bowel movements
Never or rarely. (question 49=0)
6. The pain is not relieved by postural change
Never or rarely. (question 23=0)
7. The pain is not relieved by antacids
Never or rarely. (question 21=0)
8. Exclusion of other structural disease that would explain the symptoms.
No question.

E1. Functional Gallbladder Disorder**Diagnostic criteria**

Must include **all** of the following:

1. Criteria for functional gallbladder and sphincter of Oddi disorders
Yes.
2. Gallbladder is present
Gallbladder has not been removed
No. (question 29=0)
3. Normal liver enzymes, conjugated bilirubin and amylase/lipase
No question. Laboratory studies needed.

E2. Functional Biliary Sphincter of Oddi Disorder**Diagnostic criteria**

Must include **both** of the following:

2.3. Rome III scoring algorithm

1. Criteria for functional gallbladder and sphincter of Oddi disorders

Yes.

Gallbladder has been removed (question 29=1)

Pain has recurred at least sometimes since gallbladder was removed (question 30>0)

2. Normal amylase/lipase

No question. Laboratory studies needed.

E3. Functional Pancreatic Sphincter of Oddi Disorder

Diagnostic criteria

Must include **all** of the following:

1. Criteria for functional gallbladder and sphincter of Oddi disorder

Yes.

2. Elevated amylase/lipase

No question.

F2: FUNCTIONAL ANORECTAL PAIN

F2a: CHRONIC PROCTALGIA

Diagnostic criteria*

Must include **all** of the following:

1. Chronic or recurrent rectal pain or aching

Pain or aching occurs more than once a month (question 57>2)

2. Episodes last 20 minutes or longer

Pain or aching lasts more than 20 min (question 58=2)

3. Exclusion of other causes of rectal pain such as ischemia, inflammatory bowel disease, cryptitis, intramuscular abscess, anal fissure, hemorrhoids, prostatitis, and coccygodynia.

No question.

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Yes. (question 60=1)

F2b: PROCTALGIA FUGAX**Diagnostic Criteria**

Must include **all** of the following:

1. Recurrent episodes of pain localized to the anus or lower rectum
Pain or aching in anorectal area occurs at least 1 day/month (question 57>1)
2. Episodes last from seconds to minutes
Pain or aching lasts seconds to minutes, up to 20 minutes (question 58=1)
3. There is no anorectal pain between episodes.
Pain in anus or rectum occurs and then completely disappears during the same day (question 59=1)

For research purposes criteria must be fulfilled for 3 months; however, clinical diagnosis and evaluation may be made prior to 3 months

2.4. Guidelines for repeat determinations of eligibility

While certain inclusion and exclusion criteria are more objective and are unlikely to change, others are more subjective and may change over time. Thus, participants who are deemed ineligible at the time of initial screening may be rescreened at a later time as follows:

- Age <18 years – the participant may be rescreened after his or her 18th birthday
 - Unwilling to participate – the participant may be rescreened after 3 months at the discretion of the investigator
 - Unable to complete gastric emptying scintigraphy – the participant may be rescreened when clinically indicated
 - Creatinine test may be repeated twice to allow for registration
-

2.5. Co-enrollment in NORIG treatment trial

- When a Gastroparesis Registry (GpR) participant enrolls in another GpCRC treatment trial such as NORIG, the visit schedule and requirements of the treatment trial take precedence over the requirements for the Registry. Registry requirements are suspended for the duration of the participant's time in the treatment trial. The GpR Closeout Form (CO) should be completed to suspend the Registry visits while the patient is enrolled in the treatment trial. The NORIG trial protocol and GpR Standard Operating Procedures I, section 6.29 provide instructions, but if you cannot find the answer to your question, call the Data Coordinating Center
 - Data requirements are not suspended while a patient participates in a GpCRC ancillary study
-

2.6. Transferring patient between studies

Procedures for transferring patients between the Gastroparesis Registry (GpR) and Nortriptyline for Idiopathic Gastroparesis Trial (NORIG) are given below. The specific procedures that need to be followed vary depending on whether the patient completed enrollment in the GpR. Please note the following definitions:

- **Enrolled in GpR** = GpR enrollment task has been run and the patient was found eligible and was enrolled (i.e., patient is in follow-up for the GpR)
- **Registered in GpR** = Registration (RG) form for GpR has been completed but patient has not enrolled in GpR (i.e., patient is in screening for the GpR or has been closed out of the GpR as ineligible)
- **Randomized in NORIG** = Randomization task was run, and the patient was found eligible and was issued a treatment assignment

1. Patient enrolled in GpR who now wants to screen for NORIG

- Whenever possible, the clinical center should wait at least 8 weeks after enrollment in the GpR before registering the patient in NORIG. The rationales for this are: (1) we want complete, fresh data in NORIG, and a patient is more likely to be willing to complete forms and procedures if there has been a noticeable duration since he/she completed forms for the GpR; and (2) to encourage patients who are likely NORIG candidates to enter directly into NORIG. The clinical center can use physician discretion regarding registering the patient (ie, patient can be registered before the suggested 8-week time limit), but this should be the exception rather than the rule
- Have the patient sign the NORIG consent form
- Complete and key the NORIG RG form but do NOT issue a new patient ID number and code
- Blood for biosample repository
 - Whole blood must be collected for plasma banking at the biosample repository even if plasma and serum were already banked for the GpR regardless of the time between enrollment in the GpR and registration in NORIG
- Blood for genetics repository
 - If not already collected, have the patient sign the NORIG genetic consent, collect a sample, and complete the NORIG Blood Collection for DNA (BC) and Genetic Consent Documentation (CG) forms
 - If blood was already collected, do not send another sample unless the yield was unsatisfactory (less than 100 µg)
 - If the yield on the sample drawn when the patient screened for the GpR was satisfactory, leave the GpR BC and CG forms in the data system and complete the NORIG BC form answering 'yes' to the question about prior blood draw for the GpR; the patient does not need to sign the NORIG genetic consent nor does the NORIG CG form need to be completed

2.6. Transferring patients between studies

- If the yield on the sample drawn when the patient screened for the GpR was unsatisfactory, have the patient sign the NORIG genetic consent form, draw the replacement sample, and complete the NORIG BC and CG forms; the GpR BC and CG forms should remain in the data system
- Lab results reported on the GpR Laboratory Results (LR) form may be used on the NORIG LR form if they were obtained within the time windows specified on the LR form. An additional blood draw to obtain thyroid stimulating hormone levels may be necessary
- All interviews and patient questionnaires (baseline history, quality of life, and patient health) must be completed anew for NORIG
- The physical exam (PE) form must be completed anew for NORIG
- If the patient is eventually randomized in NORIG, complete the GpR Closeout (CO) form to suspend the patient's participation in the GpR. You do not need to complete the Missed or Incomplete Visit (MV) form for the missed GpR follow-up visits. The patient remains enrolled in the GpR while participating in NORIG, but the patient is not subject to completion of GpR visits; have the patient complete NORIG follow-up visits and forms
- Retain all GpR forms completed for the patient in the patient's GpCRC file
- Retain the patient's GpR visit windows schedule since it will be needed once NORIG is completed.

2. Patient registered in GpR but never enrolled, now wants to register in NORIG

- The patient should be closed out of the GpR by completing and keying the GpR Registry Enrollment (EN) form to document the reason(s) why the patient didn't enroll in the GpR. Answer as many of the questions in sections B, C, D, and E of form EN as you can, coding an item as 'm' if you do not know the answer; if the patient is eligible for the GpR but is opting to go directly into NORIG, answer 'no' to item 15 (no longer consents) and check 'Other reason' in item 16c and write in 'opted to go directly into NORIG'
- Have the patient sign the NORIG consent form
- Complete and key the NORIG Registration (RG) form but do NOT issue a new patient ID number and code
- Blood for biosample repository
 - If more than 4 weeks have elapsed since the previous blood draw or if serum and plasma were not obtained for the GpR, you must do the blood draw for plasma for NORIG
 - If less than 4 weeks have elapsed since the previous blood draw for serum and plasma and the serum and plasma have been kept frozen or were sent to the repository at Fisher:
 - The blood draw for plasma does not need to be repeated

2.6. Transferring patients between studies

- Transcribe information from the GpR Blood Processing for Plasma and Serum (BP) form to the NORIG BP form; the date in item 4 of the NORIG BP form should be the current date, but enter the actual date of blood draw (ie, the date in item 9 on the GpR BP form) in item 9 of the NORIG BP form; when you are asked to apply duplicate labels to the NORIG BP form, write in the label information and in the margin write “see GpR BP form”; key the NORIG BP form. If the GpR BP form has been keyed, it can remain in the data system.
 - Blood for genetics repository
 - If not already collected, have the patient sign the NORIG genetic consent and collect a sample and complete the NORIG BC and CG forms
 - If blood was already collected, do not send another sample unless the yield was unsatisfactory
 - If the yield on the sample drawn when the patient screened for the GpR was satisfactory, key the GpR BC and CG forms (if not already keyed) and complete the NORIG BC form answering yes to the question about prior blood draw for the GpR; the patient does not need to sign the NORIG genetic consent nor does the NORIG CG form need to be completed
 - If the yield on the sample drawn when the patient screened for the GpR was unsatisfactory, then have the patient sign the NORIG genetic consent form, draw the replacement sample, and complete the NORIG BC and CG forms (the GpR BC and CG forms can remain in the data system)
 - Interviews and questionnaires must be completed on the NORIG forms
 - The NORIG Baseline Medical History (BH) form should be completed anew – it is different from the GpR BH form
 - Data from GpR BD, PI, QF, and SE forms may be transcribed to the corresponding NORIG forms if they have been completed within the past 4 weeks. If more than 4 weeks have elapsed, then these forms should be completed anew for NORIG
 - The patient should complete the NORIG Pagi-SYM (GD) form anew
 - The physical exam (PE) form must be completed anew
 - Data from the GpR Gastric Emptying Scintigraphy Documentation (GE) and Upper Endoscopy Documentation (EG) forms may be transcribed to the corresponding NORIG forms if the date of the procedure falls within the correct window (please refer to the NORIG inclusion criteria for the correct dates/windows of GE and EG procedures)
 - Retain all GpR forms completed for the patient in the patient’s GpCRC file.
- 3. Patient registered in NORIG, but found to be ineligible, now wants to register in the GpR**
- The patient should be closed out of NORIG by completing and keying the NORIG Randomization (RZ) form to document the reason(s) the patient was found ineligible
 - Have the patient sign the GpR consent form
 - Complete and key the GpR RG form but do NOT issue a new patient ID number and code

2.6. Transferring patients between studies

- Blood for serum and plasma repository
 - Draw whole blood for serum and plasma banking in the GpR
- Blood for genetics repository
 - If blood was not already collected, have the patient sign the GpR genetic consent and collect a sample and complete the GpR BC and CG forms
 - If blood was already collected, do not send another sample unless the yield was unsatisfactory
 - If the yield on the sample drawn when the patient screened for NORIG was satisfactory, make sure that the NORIG BC and CG forms have been keyed. Complete the GpR BC form: answer “No” to item 9 on the GpR BC form and write “collected when screening for NORIG” in the specify line. Key the GpR BC form. The patient does not need to sign the GpR genetic consent and the GpR CG form does not need to be completed.
 - If the yield on the sample drawn when the patient screened for NORIG was unsatisfactory, then have the patient sign the GpR genetic consent form, draw the replacement sample, and complete the GpR BC and CG forms (the NORIG BC and CG forms can remain in the data system)
- Interviews and questionnaires must be completed on the GpR forms
 - Data from NORIG Beck Depression Inventory (BD), Pagi-SYM (GD), and State-Trait Anxiety (SE) forms may be transcribed to the corresponding GpR forms if they have been completed within the past 4 weeks. If more than 4 weeks have elapsed, then these forms should be completed anew for GpR
 - Patient should complete the GpR BH, PE and QF forms anew even if they were completed for NORIG
- Data from the NORIG Gastric Emptying Scintigraphy Documentation (GE) and Upper Endoscopy Documentation (EG) forms may be transcribed to the corresponding GpR forms if the date of the procedure falls within the correct window (please refer to the GpR inclusion criteria for the correct dates/windows of GE and EG procedures)
- Retain the NORIG forms in the patient’s GpCRC file

These procedures are complicated and there are bound to be problems when it comes to applying the protocols to real patients. As always, contact the DCC if you have questions or if you run into problems when trying to key forms or enroll/randomize a patient.

2.7. Roll over into Gastroparesis Registry after completion of NORIG

- Patients who complete participation in NORIG should resume participation in the Gastroparesis Registry (if previously enrolled in the Registry) or be invited to join the Gastroparesis Registry (if not previously enrolled). A NORIG Closeout (CO) form should be completed at the f18 visit (or at the close of the f18 visit window) for all patients randomized in NORIG.
 - If the patient was previously enrolled in the Gastroparesis Registry, the patient resumes participation in the Registry by completing the follow-up visit that is open on the patient's Registry visit windows guide.
 - If the patient was not previously enrolled in the Gastroparesis Registry, the patient will be consented for the Registry and will receive a new visit windows schedule upon the keying of the NORIG CO form into the database. This new visit windows schedule will use the NORIG randomization date as the effective enrollment date into the Gastroparesis Registry.
-

2.8. Consenting roll over patients for NORIG

If the patient previously enrolled in NORIG

- Consent as for a new GpR patient

If the patient previously consented to DNA banking as part of NORIG

- Patient does not need to sign new consent for DNA banking as part of GpR
-

2.9. Enrollment and eligibility checking

Enrollment steps

- Complete collection of all required screening data and key all baseline data forms within 16 weeks of registration date
- Run electronic check on eligibility (i.e., run the Enrollment Task and resolve any missing items or ineligibility conditions)
- Run the Enrollment Task; if the patient is eligible, this task will officially enroll the patient in the Registry and materials needed in follow-up will be generated (i.e., labels, visit time windows)

Overriding eligibility criteria

- Requests overriding eligibility criteria must be made in writing to the DCC (direct the request to Aynur Ünalp-Arida); the request must specify the eligibility criteria for which override is requested and the request must be justified; the request must come from the principal investigator of the clinical center
- The DCC may require agreement to the override from other GpCRC investigators
- Override requests require time to review and the review process will not be shortened

Enrollment date

- The date the clinical center runs the Enrollment Task and enrolls the patient
 - The “time zero” for reckoning the time windows specified on the patient’s Registry visit time window guide is the date of enrollment
-

GpR SOP Part I: Clinical Center Operations

3. Certification

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3.1. Certification overview

What is certification?

- It is an internal (i.e., related to the study) procedure designed to identify the staff responsible for specific data items or data collection procedures or decisions about eligibility
- It is a managerial and quality assurance tool for the study

Who and what does it apply to?

- It applies to:
 - Gastroparesis Registry staff
 - Each clinical center
- Certification for the Gastroparesis Registry is required before any patient visits or data collection may occur; patients may not begin any screening examinations, sign any consent statements, or complete any study forms until the clinical center has been certified for the study
- More than one staff member may be certified for a function and it is recommended that more than one staff member be certified for a function

Why do we require it?

- Primary purpose is to help assure consistent conduct of the study over time, within and across clinical centers. The conduct of procedures should be similar across patients and in serial testing of the same patient over the duration of follow-up.
- Study procedures may vary from the usual practice of a participating clinical center, but it is important that methods be carried out in the same manner within and across clinical centers.
- It identifies the staff and sites that carry out study procedures and identifies to staff that they and their site are a part of the Gastroparesis Registry study.
- It provides a mechanism for tracking who collected key data items or made key decisions.
- The certification process may help a clinical center prepare for study activities by presenting the training, facility, and equipment needs in an organized fashion and requiring acquisition or completion of these items before study specific activities may begin.

Is separate certification in each GpCRC study required?

- Certification for Gastroparesis Registry procedures will constitute the initial round of GpCRC certification activities. When additional studies are about to begin patient activities, certification requirements related to the specific study that is to be started will be issued through notification of each clinical center by a numbered Policy and Procedure Memorandum.

3.2. Clinical center certification

General comments

- Each clinical center participating in the Gastroparesis Registry must be certified for that participation
- Completion of the Clinical Center Certification (CC) form will be required
- IRB approval for the Gastroparesis Registry protocol and consents will be required

Purpose of clinical center certification

- Provide information regarding how the clinical center will conduct different aspects of the protocol and who will staff the study
- Guide a clinical center through the steps of getting ready for the Gastroparesis Registry – provide a checklist of what needs to be in place before patient activities begin

Requirements for certification of a site

- Complete the Clinical Center Certification (CC) form
 - Certify at least one person for each function that requires certification (a person may be certified for more than one function)
 - Obtain IRB approval of the most current Gastroparesis Registry protocol and consent documents
 - Receive written notice of approval (email) from the Data Coordinating Center that the site is certified
-

3.3. Personnel certification

Staff functions requiring certification

- Clinical Coordinator
- Study Physician
- Data Entry Technician

Requirements

- Everyone
 - Read the Gastroparesis Registry protocol and SOP I: Clinical Center Operations
 - Complete the Knowledge Assessment (KA) form; this is a written general knowledge assessment about the Registry (open book)
 - Complete the Personnel Certification (PC) form; this form identifies the functions applied for and provides an assurance of data confidentiality and integrity
- Additional requirements for Study Physician
 - Study Physician must be an MD preferably a gastroenterologist
- Additional requirements for Data Entry Technician
 - Complete the Data Entry Certification/Decertification Request (DC) form
 - Complete the data system tutorial

Process

- Send required materials to the DCC
- The DCC will send written notice of approval for certification or pending certification
- Each staff member will be issued a Personnel Identification Number (PIN)

Staff PINs

- Each staff member certified for at least one function will be issued a PIN which will consist of 3 digits – the first digit will identify the clinical center and the next two digits will be a sequential number assigned by the Data Coordinating Center
 - The PIN is used when completing forms
 - The Data Entry Technician uses his/her PIN when signing on to the GpR data system
 - Staff can be certified for more than one function but will have only one PIN
-

GpR SOP Part I: Clinical Center Operations**4. Human subjects**

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4.1. Background

Consent to participation in the Gastroparesis Registry must be completed before screening for the study may begin. The patient must consent to procedures offered to and performed on him/her for screening, as well as to the follow-up visits which the patient will face in the future.

The consent process is a dynamic process involving explanations, time to think, questions, clarifications, and advice that a patient may seek from relatives, friends or anybody else considered relevant. We wish to inform the prospective participant as much as possible and as accurately as possible about what will be offered to him/her, how it will be done, what are the reasonable risks and benefits, what are the alternatives, and what is expected of the patient. We wish to answer patients' questions in a consistent and complete way.

The Gastroparesis Registry consent process has three major stages:

- The patient is asked to consent to screening and enrollment into the Gastroparesis Registry
 - The patient is asked to consent to the collection, storage, and use of blood samples for genetic research
 - The patient is asked to sign the HIPAA authorization to disclose protected health information
 - Once the consent forms have been signed, proceed with the completion of the Registration (RG) form. At the end of the screening process, the patient is asked to re-affirm their consent on the Enrollment (EN) form
-

4.2. Institutional Review Board process

Two prototype consent statements have been prepared for the Gastroparesis Registry:

- Consent for screening and enrollment in the Registry
- Consent for the collection, storage, and use of blood samples for current and future genetic research

Clinical centers are expected to use these materials in their submissions to their Institutional Review Boards (IRBs) for approval to participate in the Gastroparesis Registry. Each clinic must send copies of the consent statements to be used in their clinic, stamped with their IRB's seal, to the Data Coordinating Center prior to initiating patient activities in the Gastroparesis Registry. Data Coordinating Center staff will review and compare the approved local consents to the prototype consents. Specific local additions to and editing of the prototypes may be required at individual institutions, but deletion of material and major rewording of text may need to be explained and justified. Once a consent form has been approved by an institution's IRB, it cannot be changed without the IRB's approval.

The study protocol, consent forms, and data collection forms will be submitted to each clinical center's IRB and to the Data Coordinating Center's IRB. Additionally, each clinical center will submit to their IRB any recruitment materials to be used at their site. A clinical center may not initiate any patient contact about the Gastroparesis Registry until the site has IRB approval for the Registry and the Data Coordinating Center has certified the site for initiation of patient activities. All study personnel will have completed training in the Protection of Human Subjects per NIH guidelines.

HIPAA authorization forms will be prepared by each clinical center according to local clinical center institutional requirements and guidelines.

4.3. Consent administration

Gastroparesis Registry consents

It is assumed that patients referred to a clinical center for screening have heard about the Gastroparesis Registry, but their level of knowledge and expectations may well differ. We wish to standardize the consent administration across clinical centers as much as possible. Administration of the Registry consents involves two tasks:

- (1) A Gastroparesis Registry staff member must sit down with the patient and review the contents of the statement; explain the risks, benefits, and responsibilities of participation; review the alternatives to participation; and answer questions.
- (2) A Gastroparesis Registry certified study physician (i.e., a Gastroparesis Registry Certified gastroenterologist) must sign the consent statement, taking overall responsibility for the patient's informed and voluntary consent.

Staff at each clinical center should be designated to carry out these tasks. The rationale for requiring that the consent statement be signed by a study physician is to help assure that the physician signing the consent is one who has a broad role in the study.

Generally, the consent statements should be offered to the patient to read through at least a day before signature is requested. The consent will then be reviewed with the patient by the staff member designated to obtain consent; the consenter may opt to read the statement to the patient, pausing to explain issues as needed. This activity should take place in a quiet, private and relaxed setting in the clinical center.

The patient should sign the consent statement in the presence of the Gastroparesis Registry staff member after all questions have been answered and when the patient has asserted orally that he/she is ready to sign the consent. After the patient has signed and dated the consent, the patient should meet with a Gastroparesis Registry study physician for the physician to sign the consent statement; ordinarily this meeting should take place on the same day that the patient signed the consent statement. The physician should ask the patient to confirm his/her voluntary consent and query the patient about any questions or concerns the patient may have about participation. Both signatures on the consent form must be in a non-erasable ink pen. If the physician cannot meet with the patient on the same day that the patient signs the consent statement, the physician may sign on another day. It is good practice to make an entry in patient's chart that the consent form was discussed and consent was obtained.

Consent for genetic research

The consent for collection and banking of blood for genetic research should be administered in the same way that the Gastroparesis Registry consent is administered, except that it should not be signed until the patient has been determined to be eligible for the Gastroparesis Registry.

4.4. Time considerations for obtaining consent

- The **Gastroparesis Registry Consent and HIPAA authorization** must be obtained at the start of the initial screening visit; documents from the referring physician (if any) should have been reviewed prior to the visit and the patient judged eligible for screening prior to the visit. Signature of this consent is required prior to sending the patient for any Gastroparesis Registry diagnostic tests. A check for signature of this consent statement occurs on the Registration (RG) form.
 - The **Registry Consent for Collection, Storage, and Use of Blood Samples for Current and Future Genetic Research** must be obtained after eligibility for the Gastroparesis Registry has been established, during screening. Signature of this consent is required prior to drawing blood for genetic research for the Gastroparesis Registry; a check for signature of this consent statement occurs on the Blood Collection for DNA (BC) form. Signature of this consent statement is not required for Gastroparesis Registry eligibility (i.e., the patient may choose not to participate in the genetic research component of the Gastroparesis Registry).
 - A patient may be given the consent statements to review prior to the initiation of screening visit to meet patient needs with respect to review time. Whenever a consent is first given to a patient for review, it should be made clear to the patient that the consent should not be signed until requested by a Gastroparesis Registry staff member. The consents may be mailed to the patient prior to screening visit. Whatever timing is used by a clinic, the patient should be allowed enough time to reflect about the proposed Gastroparesis Registry procedures, pose questions, and consult with other individuals that he/she considers relevant to their participation in the Gastroparesis Registry. Patients may request and should be given time to "think it over" at home and come back at a later time.
-

4.5. Consent handling

- Signed consent statements are important legal documents. These signed statements should be kept in the patient's Gastroparesis Registry clinical center file together with his/her other Gastroparesis Registry forms and documents. These forms are not part of the individual's institutional medical record, but part of his/her study record in the Gastroparesis Registry. Consent statements will be examined during site visits.
 - Consents should be annotated with the patient's study identifiers (ID number and code).
 - The Gastroparesis Registry consent statement is an “all or none” form. The patient either accepts it in its entirety and signs it, or does not. The patient must consent to the evaluation procedures, the follow-up evaluations, and the banking of his/her serum and plasma. If the patient refuses any part, the patient may not enroll in the Gastroparesis Registry.
 - The Gastroparesis Registry Consent for Genetic Research has been made a separate consent statement so that the patient can opt out of genetic research and still participate in the Gastroparesis Registry.
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4.6. Informing participants of changes to consent statement after enrollment

As new data become available during the conduct of the Gastroparesis Registry, the consent statements may need to be changed to reflect the current assessment of risks and benefits to participants in the study.

Procedures for dissemination of revisions of consent statements from the DCC

- Changes deemed necessary will be made to the prototype consent statements
- Revisions of the prototype consent statements will be distributed to sites via a numbered Policy and Procedure Memorandum (PPM) with instructions to submit the revised consent to their IRB

Procedures for reviewing changes to consent statements with participants

- Clinical center personnel will develop a chronology of IRB approved changes to the consent statements used at their site
 - At each follow-up visit, staff will use the chronology of consent changes to review with the participant any changes to the consent since the last visit. This review does not require obtaining the participant's signature on a new consent statement, unless the local IRB requires obtaining a signature.
 - Review changes to the consent statements with participants at follow-up visits
 - This review process is not intended to be a reaffirmation of consent. The clinical center, if required by their local IRB, may develop procedures for reaffirmation of consent.
-

4.7. HIPAA considerations

Gastroparesis Registry study staff have access to patient health information and to patient identifiers, such as name, address, and telephone number. Study records are to be kept in a secure place. Only people working on the Gastroparesis Registry should have access to these records. However, these records could be reviewed to make sure that the study is being done as it should. People who may see medical records supporting study records are:

- Officials of your institution
- Your institution's research ethics committee
- Monitors from the GpCRC Data Coordinating Center at the Johns Hopkins University, or other individuals selected by the GpCRC Steering Committee to monitor the study
- Members of the Data and Safety Monitoring Board (DSMB) to monitor overall progress of the study
- Government officials from the Office of Human Research Protections or the National Institutes of Health

Each clinical center should take steps to protect patient privacy. The assigned patient ID number and code should be used to identify patients on forms and in the data files. Personal information such as name, address, and telephone number should be kept only at the clinical center where a patient completes visits.

People outside the clinical center who will receive Gastroparesis Registry study data include:

- The GpCRC Data Coordinating Center at the Johns Hopkins University in Baltimore, Maryland (or its successor) to maintain the central study database
- The GpCRC Data and Safety Monitoring Board to review the Gastroparesis Registry data for performance and safety
- The NIDDK Genetics Repository at Rutgers, the State University of New Jersey in New Brunswick, New Jersey (or its successor) will receive patients' blood to obtain DNA; the blood samples for a particular patient will be identified by the patient's study ID number and code, not by name
- The NIDDK Biosample Repository at Fisher Bioservices in Germantown, Maryland (or its successor) will receive patients' serum and plasma; the samples for a particular patient will be identified by the patient's study ID number and code, not by name
- The GpCRC investigators, as well as outside researchers, to analyze and report Gastroparesis Registry study data. Patient identity will not be disclosed in any reports or publications resulting from the study. While the Gastroparesis Registry is ongoing, the use of the Gastroparesis Registry study data must be approved by the GpCRC Steering Committee and by the research ethics committee at your institution.

4.7. HIPAA considerations

Patient agreement to join the Gastroparesis Registry indicates that the patient also agrees to the use of study data as described above. If a patient does not agree to the described uses of study data, the patient may not participate in the Gastroparesis Registry. The only exception is refusal to provide blood for genetic research; patients may refuse to provide blood for genetic research and still enroll in the Gastroparesis Registry.

GpR SOP Part I: Clinical Center Operations

5. Study visits

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GpR SOP Part I: Clinical Center Operations

5.1. Overview of visit schedule

Screening (must be completed within 16 weeks of registration date)

- b: Consent, baseline medical history, physical exam, fasting blood draw for serum and plasma banking; blood draw for DNA banking and any laboratory measures (hematology, chemistries, HbA1c, liver panel, erythrocyte sedimentation rate, anti-nuclear antibody [ANA], scleroderma antibody [Scl-70], C-reactive protein [CRP], serum protein electrophoresis [SPEP]) if not available from archival records; upper endoscopy and gastric emptying scintigraphy as needed; IDIOMS form; questionnaires on quality of life (Beck Depression Inventory, Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL], State Trait Anxiety Inventory, SF-36 Health Survey); diet (Brief food questionnaire); and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM], Rome III Diagnostic Questionnaire and Brief Pain Inventory). The last form to be completed at screening should be the Registry Enrollment form (EN) which reaffirms the patient's consent to participate in the Gastroparesis Registry.

Enrollment

- en: Enrollment is an event, not a visit; enrollment occurs when the clinical center staff runs the enrollment task on the Gastroparesis Registry data system and the patient is found to be eligible.

Follow-up

- f016: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f032: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).

GpR SOP Part I: Clinical Center Operations

5.1. Overview of visit schedule

- f048: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), fasting blood draw for serum and plasma banking, collection of findings from any interim upper endoscopy and gastric emptying scintigraphy as needed; IDIOMS form; questionnaires on quality of life (Beck Depression Inventory, Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL], State Trait Anxiety Inventory, SF-36 Health Survey); diet (Brief food questionnaire); and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM], Rome III Diagnostic Questionnaire and Brief Pain Inventory).
- f064: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f080: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f096: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), fasting blood draw for serum and plasma banking, collection of findings from any interim upper endoscopy and gastric emptying scintigraphy as needed; IDIOMS form; questionnaires on quality of life (Beck Depression Inventory, Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL], State Trait Anxiety Inventory, SF-36 Health Survey); diet (Brief food questionnaire); and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM], Rome III Diagnostic Questionnaire and Brief Pain Inventory).

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5.1. Overview of visit schedule

- f112: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f128: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed; IDIOMS; questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f144: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), fasting blood draw for serum and plasma banking, collection of findings from any interim upper endoscopy and gastric emptying scintigraphy as needed; IDIOMS form; questionnaires on quality of life (Beck Depression Inventory, Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL], State Trait Anxiety Inventory, SF-36 Health Survey); diet (Brief food questionnaire); and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM], Rome III Diagnostic Questionnaire and Brief Pain Inventory).
- f160: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed, questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).
- f176: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), collection of findings from any interim upper endoscopy or gastric emptying scintigraphy if needed, questionnaires on quality of life (Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL]; and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM] and Brief Pain Inventory).

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5.1. Overview of visit schedule

- f192: Follow-up medical history, physical examination, blood draw for laboratory measures if needed (HbA1c required for diabetic patients), fasting blood draw for serum and plasma banking, collection of findings from any interim upper endoscopy and gastric emptying scintigraphy as needed; IDIOMS form; questionnaires on quality of life (Beck Depression Inventory, Patient Assessment of Upper Gastrointestinal Disorders Quality of Life [PAGI-QOL], State Trait Anxiety Inventory, SF-36 Health Survey); diet (Brief food questionnaire); and gastroparesis symptoms (Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity [PAGI-SYM], Rome III Diagnostic Questionnaire and Brief Pain Inventory).
-

GpR SOP Part I: Clinical Center Operations

5.2. Visits, data forms, and procedures

Phase/ Visit	Form abbr	Procedure
Screening		
	RG	Registration (document consent, sociodemographics, assign IDs)
	BH	Baseline Medical History
	PL	Patient Location (patient contact information)
	FQ	Food Questionnaire Documentation (completion of Block Brief Food Questionnaire)
	EG	Upper Endoscopy Documentation
	GE	Gastric Emptying Scintigraphy Documentation
	LR	Laboratory Results (The following laboratory test results are required to be recorded during screening: hematology, hepatic panel, clinical chemistry, HbA1c, antinuclear antibody [ANA], scleroderma antibody [Scl-70], serum eletrophoresis [SPEP], C-reactive protein [CRP])
	QF	SF-36 Health Survey
	CG	Genetic Consent Documentation
	BC	Blood Collection for DNA
	BP	Blood Processing for Plasma and Serum
	GP	NIDDK Genetics Phlebotomy Form
	PE	Physical Examination
	GD	Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM)
	UG	Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)
	ID	Investigator Derived Independent Outcome Measure Scores (IDIOMS)
	BD	Beck Depression Inventory
	FD	Rome III Diagnostic Questionnaire
	PI	Brief Pain Inventory
	SE	State-Trait Anxiety Inventory (Self-Evaluation Questionnaire)
	EN	Registry Enrollment

GpR SOP Part I: Clinical Center Operations

5.2. Visits, data forms, and procedures

Follow-up phase

16 week follow-up visit

f016	FH	Follow-up medical history
	PE	Physical Examination
	PI	Brief Pain Inventory
	GD	PAGI-SYM questionnaire
	UG	PAGI-QOL questionnaire
	ID	IDIOMS questionnaire
	EG	Endoscopy Documentation (if upper endoscopy is reported on form FH)
	GE	Gastric Emptying Scintigraphy Documentation (if gastric emptying test is reported on form FH)
	LR	Laboratory test results will be recorded if available during follow-up (hematology, hepatic, clinical chemistry, if needed; HbA1c required for diabetic patients)
	PL	Patient Location (update as needed)

32 week follow-up visit

f032		Same as 16 week follow-up visit
------	--	---------------------------------

48 week follow-up visit

f048		<i>The patient should be in a fasting state for this follow-up visit.</i>
	FH	Follow-up medical history
	PE	Physical Examination
	BP	Blood processing for plasma and serum
	FQ	Food Questionnaire Documentation (completion of Block Brief Food Questionnaire)
	EG	Upper Endoscopy Documentation (if upper endoscopy is reported on form FH)
	GE	Gastric Emptying Scintigraphy Documentation (if gastric emptying test is reported on form FH)
	GD	PAGI-SYM questionnaire
	UG	PAGI-QOL questionnaire
	ID	IDIOMS questionnaire
	BD	Beck Depression Inventory
	FD	Rome III Diagnostic Questionnaire
	SE	State-Trait Anxiety Inventory (Self-Evaluation Questionnaire)
	QF	SF-36 Health Survey
	PI	Brief Pain Inventory
	LR	Laboratory tests as available during follow-up (hematology, hepatic, clinical chemistry, if needed; HbA1c required for diabetic patients)
	PL	Patient Location (update as needed)

GpR SOP Part I: Clinical Center Operations

5.2. Visits, data forms, and procedures

64 week follow-up visit f064	Same as 16 week follow-up visit
80 week follow-up visit f080	Same as 16 week follow-up visit
96 week follow-up visit f096	<i>The patient should be in a fasting state for this follow-up visit.</i> Same as 48 week follow-up visit
112 week follow-up visit f112	Same as 16 week follow-up visit
128 week follow-up visit f128	Same as 16 week follow-up visit
144 week follow-up visit f144	<i>The patient should be in a fasting state for this follow-up visit.</i> Same as 48 week follow-up visit
160 week follow-up visit f160	Same as 16 week follow-up visit
176 week follow-up visit f176	Same as 16 week follow-up visit
192 week follow-up visit f192	<i>The patient should be in a fasting state for this follow-up visit.</i> Same as 48 week follow-up visit
As needed CO	Registry closeout

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5.3. Guide for screening visit at baseline

Procedures

- Obtain signed consent for the Gastroparesis Registry (consent form(s) and HIPAA authorization form)
- Obtain permission to abstract data from patient's medical records
- Initiate data collection for screening and baseline values
 - Physical exam and anthropometric measurements (height, weight, waist circumference, hip circumference, temperature, blood pressure, resting radial pulse, respiratory rate)
 - Interview for baseline medical history (responses may be modified or expanded upon chart review)
 - Laboratory testing (hematology, hepatic, clinical chemistry, HbA1c, ANA, Scl-70, CRP, SPEP)
 - Specimen banking (serum, plasma, and DNA)
 - Upper endoscopy results documentation
 - Gastric emptying scintigraphy results documentation
 - Questionnaires regarding quality of life, diet and gastroparesis symptoms
- Obtain patient location information

Data collection forms

- Forms completed for all patients
 - RG Registration (document consent, sociodemographics, assign IDs)
 - BH Baseline Medical History
 - PL Patient Location (patient contact information)
 - FQ Food Questionnaire Documentation (completion of Block Brief Food Questionnaire)
 - EG Upper Endoscopy Documentation
 - GE Gastric Emptying Scintigraphy Documentation
 - LR Laboratory Results (completion of all laboratory test results required during screening: hematology, hepatic, clinical chemistries, HbA1c, ANA, Scl-70, SPEP, and CRP)
 - QF SF-36 Health Survey
 - CG Genetic Consent Documentation
 - GP NIDDK Genetics Phlebotomy Form
 - BC Blood Collection for DNA
 - BP Blood Processing for Plasma and Serum
 - PE Physical Examination
 - GD Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM)
 - UG Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)
 - ID Investigator Derived Independent Outcome Measure Scores (IDIOMS)

GpR SOP Part I: Clinical Center Operations

5.3. Guide for screening visit at baseline

- BD Beck Depression Inventory
- FD Rome III Diagnostic Questionnaire
- PI Brief Pain Inventory
- SE State Trait Anxiety Inventory (Self-Evaluation Questionnaire)
- EN Registry Enrollment

Forms for clinical center use only

- PL - Patient Location
- Medical records release (use local form)
- GP - NIDDK Genetics Phlebotomy Form

Before the patient leaves the clinical center

- Register patient on clinic data system
- Apply labels to forms as needed if they are taking any of the forms with them

After the patient leaves the clinical center

- Ship whole blood specimen for DNA extraction to NIDDK Genetics Repository by overnight Fed Ex delivery service
 - Serum and plasma tubes are centrifuged and separated into aliquots of .5mL each into corresponding pre-labeled cryovials and stored at -70° C at clinical center
 - Frozen serum and plasma samples are batch shipped to NIDDK Biosample Repository every month
 - Key completed data forms
 - Run Enrollment task in web-based data management system
 - Set up Gastroparesis Registry chart for patient and file the completed forms. Use visit windows guide generated at enrollment to prepare forms and labels that will be used at visit f016
-

GpR SOP Part I: Clinical Center Operations

5.4. Visit windows: enrollment and follow-up

- **Enrollment** must occur within 16 weeks of initiating screening (completion of the Registration (RG) form)
 - **f016:** window opens 8 weeks from date of enrollment and runs through 24 weeks after enrollment, ideal date is 16 weeks (112 days) after enrollment date
 - **f032:** window runs from (24 weeks+1 day) through 40 weeks, must be at least 8 weeks after f016; ideal date is 32 weeks (224 days) after enrollment date
 - **f048:** window runs from (40 weeks+1 day) through 56 weeks, must be at least 8 weeks after f032; ideal date is 48 weeks (336 days) after enrollment date
 - **f064:** window runs from (56 weeks+1 day) through 72 weeks, must be at least 8 weeks after f048; ideal date is 64 weeks (448 days) after enrollment date
 - **f080:** window runs from (72 weeks+1 day) through 88 weeks, must be at least 8 weeks after f064; ideal date is 80 weeks (560 days) after enrollment date
 - **f096:** window runs from (88 weeks+1 day) through 104 weeks, must be at least 8 weeks after f080; ideal date is 96 weeks (672 days) after enrollment date
 - **f112:** window runs from (104 weeks+1 day) through 120 weeks, must be at least 8 weeks after f096; ideal date is 112 weeks (784 days) after enrollment date
 - **f128:** window runs from (120 weeks+1 day) through 136 weeks, must be at least 8 weeks after f112; ideal date is 128 weeks (896 days) after enrollment date
 - **f144:** window runs from (136 weeks+1 day) through 152 weeks, must be at least 8 weeks after f128; ideal date is 144 weeks (1008 days) after enrollment date
 - **f160:** window runs from (152 weeks+1 day) through 168 weeks, must be at least 8 weeks after f144; ideal date is 160 weeks (1120 days) after enrollment date
 - **f176:** window runs from (168 weeks+1 day) through 184 weeks, must be at least 8 weeks after f160; ideal date is 176 weeks (1232 days) after enrollment date
 - **f192:** window runs from (184 weeks+1 day) through 200 weeks, must be at least 8 weeks after f176; ideal date is 192 weeks (1344 days) after enrollment date
-

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5.5. Interim (unscheduled) visits or telephone contacts

- Unscheduled visits or telephone contacts may occur as needed. No time windows or minimum time separations are imposed for such visits or contacts.
 - Data collection forms are not required at interim visits. However, if lab results are available or procedures such as endoscopy or scintigraphy are performed, then the corresponding data forms (LR, EG, GE) should be completed using visit code 'n'.
 - If gastroparesis symptom exacerbation occurs for a Gastroparesis Registry patient between scheduled Gastroparesis Registry visits, complete the Interim Event Report (IE) form; the visit code for the form will be 'n'. If more than one event is reported on the same calendar day (i.e., same date in item 4 for all events), use visit code 'n' for first event, 'n' for the second event, etc.
-

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6.1. Assignment of study identifiers

What

- The GpCRC uses 2 identifiers for patients
 - ID number (4 digits)
 - ID code (3 alphabetic characters)
- These identifiers help assure confidentiality of patient identity

Materials

- ID number and code labels received from the Data Coordinating Center
- Registration (RG) form

When

- Screening visit b

By whom

- Clinical Coordinator

Procedures

- Complete the Registration (RG) form; if the patient remains eligible at the close of the form, assign the ID number and code by peeling a label off the label sheet and affixing it to the specified item on form RG
- The patient will be known by these IDs for the duration of the GpCRC, including participation in any other GpCRC studies
- Key the Registration (RG) form into Gastroparesis Registry data system; this must be the first form keyed and no other forms may pre-date the date of the RG form

Comments

- Once an ID number and its associated ID code are assigned, these IDs must be used by the patient for the duration of the GpCRC and cannot be changed
 - Do NOT reassign or reuse IDs assigned to patients found to be ineligible or who refuse enrollment
-

6.2. Gastric emptying scintigraphy procedure

Egg Beaters Gastric Emptying Scintigraphy

The standard scintigraphy meal will consist of a low fat Egg Beaters meal radiolabelled with 0.5 -1 mCi 99Tc; which is scrambled and cooked. This is served with 2 pieces of toast, jam, and water. The meal has a caloric value of 255 kcal (nutritional composition: 72% carbohydrate, 24% protein, 2% fat, and 2% fiber). The meal is adopted from the multi-center study using a low fat meal by Tougas et al.

Items needed for Egg Beaters Gastric Emptying Scintigraphy

- Egg Beaters (egg substitute): 99% real eggs, cholesterol free, fat free, low calorie (120 g Egg Beater, 60 kcal, approx two large eggs)
- 2 slices of bread (120 kcal),
- Strawberry jam (30 g, 74 kcal)
- Water (120 ml).
- Technetium-99m 0.5 -1 mCi

Gastric emptying studies are generally performed in the morning. Patient should be fasting overnight or for at least 6 hours. (It is all right for the patient to have taken medications with some water on arising).

Patients should generally stop medications that can affect gastric emptying for 3 days prior to the test. This includes prokinetic agents, narcotic analgesics, and anticholinergic agents.

Diabetic patients should have a reasonable glucose level for the test. Diabetic patients generally will test and record their blood sugar prior to the test. Generally the fasting glucose should be between 75 and 275 mg/dL. Diabetic patients should self administer their insulin with meal ingestion, generally ½ what they take normally.

To prepare the meal, the Egg Beaters is poured into a bowl, sprinkled with 0.5 - 1 mCi 99Tc sulfur-colloid marker on top, mixed, and cooked in a microwave. Alternative is to use a skillet (nonstick frying pan). The Egg Beater mixture is stirred once or twice during cooking and is cooked until it has the consistency of an omelet (3-5 min). The bread is toasted. Jelly is spread on the bread, and a sandwich is made of the jellied bread and cooked egg mixture. The subject completes the sandwich meal within 10 minutes. The staff technologist records how long it takes the subject to consume the meal and how much they consume.

Immediately after meal ingestion, the subject will be placed in front of a gamma camera with images taken in the 140 keV 99Tc peak with a 20% window (140 keV ± 10%). 1 minute of anterior and 1 minute of posterior measurements will be taken. Subsequent images are taken at least 1, 2, and 4 hours after meal ingestion. It would be helpful to obtain these images at 30 minutes, 1 hour, 2

6.2. Gastric emptying scintigraphy procedure

hours, 3 hours, and 4 hours after meal ingestion. This may help improve the test. The times of the images should be recorded.

In the time between images, subjects can be sitting, standing, or walking but should remain in close proximity to the nuclear medicine section.

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.

References:

1. Tougas GH, Eaker EY, Abell T, et al. Assessment of gastric emptying using a low fat meal: establishment of international control values. *Am J Gastroenterol* 2000;95(6):1456-62.
 2. Vijayamkumar V, Briscoe EG, Boysen TL, Jimenez YM. Assessment of the practical role of a low-fat-meal solid gastric emptying study. *J Nucl Med Technol* 2006;34:82-85.
-

6.3. Gastric Emptying Scintigraphy Documentation (GE form)

Purpose

- To record results from gastric emptying scintigraphy to determine eligibility and patient category

When

- Screening visit b (the gastric emptying scintigraphy must have been performed at a Gastroparesis Registry clinic within 6 months prior to enrollment)
- As needed during follow-up, if a new scintigraphy test is performed, findings should be captured on the respective follow-up visit GE form.

Procedure

- Study Physician completes the form using the gastric emptying scintigraphy report
 - Any necessary information not contained in the report should be gathered from the patient immediately after the test
-

6.4. Upper Endoscopy Documentation (EG form)

Purpose

- To document the results of the upper gastrointestinal endoscopy to determine patient eligibility

When

- Screening visit b (the upper gastrointestinal endoscopy must have been performed within 12 months prior to enrollment)
- As needed during follow-up, if a new endoscopy is performed, findings should be captured on the respective follow-up EG form

Procedure

- Study Physician or Clinical Coordinator completes the form using the available reports (surgical and histology) of the upper gastrointestinal endoscopy procedure
 - A copy of the available reports should be attached to the form
-

6.5. Baseline Medical History (BH form)

Who

- Complete for all Registry patients
- Study Physician and Clinical Coordinator sign the form

What

- The form queries:
 - Symptoms of gastroparesis
 - Medical history (answer items based on information from all sources available to you)
 - Medication used currently and in the past 6 months and corresponding response

When

- Screening visits

How

- Mix of interview data and data obtained by chart review
 - Other questions on the BH form can be answered by interview with the patient – ie, use all sources to get the most accurate information that you can
-

6.6. Follow-up Medical History (FH form)

Who

- Complete for Database patients of all ages
- Study Physician and Clinical Coordinator sign the form

What

- The form queries/reviews
 - Change in patient's symptoms
 - Medical history diagnoses and procedures since the last visit
 - Medication use since the last visit

When

- Visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176 and f196

How

- Mix of interview data and data obtained by chart review
 - Questions on the FH form can be answered by interview with the patient – i.e., use all sources to get the most accurate information that you can
-

6.7. Physical Examination (PE form)

Who

- All Registry patients

What

- Anthropometry
 - Height
 - Weight
 - Waist circumference
 - Hip circumference
- Vital signs
 - Temperature
 - Blood pressure
 - Resting radial pulse
 - Respiratory rate
- System review
 - Chest and lungs
 - Heart
 - Abdomen
 - Abdomen abnormality
 - Liver and spleen
 - Nervous system

How

- Ideally, use a stadiometer for height measurement
 - Ideally, use the Gulick II tape measure for waist and hip measurement; this device may be obtained from www.fitnessmart.com (608-735-4718, model 67019, listed at \$36); it is manufactured by Country Technology Inc: 608-735-4718
 - See the sections that follow which detail the protocol for measurement of height, weight, waist circumference, and hip circumference
-

6.8. Height and weight measurements

Height measurements

- Height may be recorded in inches or centimeters
- Ideally, a wall-mounted stadiometer with a horizontal measuring block (or fixed angle) is used; other height measuring devices are acceptable
- Follow the manufacturer's recommendation regarding method and frequency of calibration of the stadiometer
- The patient stands erect on the platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane defined by the lower margin of the bony orbit (the bony socket containing the eye) and the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear))
- The horizontal measuring block is brought down snugly, but not tightly, on the top of the head
- Record the height to the nearest tenth of the unit of measurement (1 decimal place)

Weight measurements

- Follow the manufacturer's recommendation regarding method and frequency of calibration of the scale
 - Weight may be recorded in pounds or kilograms
 - Ideally, weight is measured in the morning after voiding and before breakfast; if this is not possible, try to measure the patient's weight at the same time of day and under the same conditions as the baseline measurements are obtained
 - Patient should be wearing light clothing (e.g, short sleeve shirt or blouse or surgical gown), shorts, socks and without shoes; pockets should be empty
 - Patient should stand still in the middle of the scale platform with head erect and eyes looking straight ahead
 - Record the weight to the nearest tenth of the unit of measurement (1 decimal place)
 - Patients who have limb amputations or who are wearing casts should have weight measured, but note this on the form on the margin (the notes may be keyed at data entry in the General Comments area of the keying)
-

6.9. Waist circumference measurement

- Waist circumference may be recorded in inches or centimeters
 - Two measurements are recorded
 - Ideally, a Gulick II Tape Measure will be used; this tape measure is designed to eliminate the guesswork by applying a known amount of tension (4 ounces) to the measuring tape; when used properly, tape tension is always 4 ounces; the self-retracting tape is kept at the desired length until the retract button is pushed
 - If an ordinary tape measure (without the special 4 ounce tension indicator device) is used, the measurement will be affected by how tightly the tape is pulled
 - Patient should be wearing light clothing (e.g., short sleeve shirt or blouse or surgical gown), shorts, socks and without shoes; pockets should be empty
 - Ideally, waist circumference is measured in the morning after voiding and before breakfast; if this is not possible, try to measure the patient's waist at the same time of day and under the same conditions as the baseline measurements are obtained
 - Patient should stand with feet together
 - Pull an appropriate amount of tape out of the housing
 - Ask the patient to bare his/her waist
 - Wrap the tape once around the waist: the measure should be taken around the abdomen horizontally at the midpoint between the highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line
 - Mark the midpoint on both sides of the patient using a washable marker
 - Patient may be asked to assist in passing the tape around the abdomen by holding the end of the tape in position
 - When the tape is positioned in the horizontal plane at the correct height, the patient should be asked to keep his/her arms at the sides and breathe naturally; ask the patient to breathe in and out and hold at the end of a normal exhalation
 - Align the tape's zero line along side of the tape graduations; pull on the end of the tensioning mechanism until you see just one colored bead
 - Record the measurement to the nearest tenth (one decimal place)
 - Remove the tape, retract the tape, and repeat the procedure
 - If the tape cannot be made horizontal across the waist markings, default to the right hip and note this in the margin of the form
-

6.10. Hip circumference measurement

- Hip circumference may be recorded in inches or centimeters
 - Two measurements are recorded
 - Ideally, a Gulick II Tape Measure will be used; this tape measure is designed to eliminate the guesswork by applying a known amount of tension (4 ounces) to the measuring tape; when used properly, tape tension is always 4 ounces; the self-retracting tape is kept at the desired length until the retract button is pushed
 - If an ordinary tape measure (without the special 4 ounce tension indicator device) is used, the measurement will be affected by how tightly the tape is pulled
 - Patient should be wearing light clothing (e.g., short sleeve shirt or blouse or surgical gown), shorts, socks and without shoes; pockets should be empty
 - Ideally, hip circumference is measured in the morning after voiding and before breakfast; if this is not possible, try to measure the patient's hips at the same time of day and under the same conditions as the baseline measurements are obtained
 - Patient should stand with feet together
 - Pull an appropriate amount of tape out of the housing
 - Ask the patient to adjust his/her clothing to allow measuring the hips over the patient's underwear
 - Wrap the tape once around the hips over the underwear: the measure should be taken at fullest part of the hips (maximum extension of the buttocks)
 - Patient may be asked to assist in passing the tape around the hips by holding the end of the tape in position
 - When the tape is positioned correctly, the patient should be asked to keep his/her arms at the sides and breathe naturally; ask the patient to breathe in and out and hold at the end of a normal exhalation
 - Align the tape's zero line along side of the tape graduations; pull on the end of the tensioning mechanism until you see just one colored bead
 - Record the measurement to the nearest tenth (one decimal place)
 - Remove the tape and repeat the procedure
-

6.11. Food questionnaire (Block Brief and FQ form)

What

- Block Brief Food Questionnaire
- Food Questionnaire Documentation (FQ) form
- Portion size illustration (part of the Block Brief Food Questionnaire booklet)

Purpose

- To determine patient's usual eating habits over the past year or so, including all meals or snacks, at home or in a restaurant or carry-out.
- To assess food frequency and quantity over the preceding year

When

- Screening visit b
- Annual follow-up visits (ie, visits f048, f096, f144, and f192)

Procedure

- Use #2 pencil and fill in the bubble areas completely
- Before giving the booklet to the patient to complete, the Clinical Coordinator must:
 - Affix the Food Questionnaire ID label in the area where the patient is instructed to complete his/her name
 - Mark the patient's four digit ID # in the bubble area of the front page of the booklet
 - Mark the date in the bubble area of the front page of the booklet – THIS IS VERY IMPORTANT TO DO CORRECTLY – when the analysis is returned by the Block staff, date is the item which will distinguish screening from follow-up questionnaires
 - Mark the patient's gender in the bubble area of the front page of the booklet
 - Mark the patient's age at last birthday in the bubble area of the front page of the booklet
- Provide the patient with:
 - #2 pencil
 - Booklet
 - Portion size illustration
- Instruct the patient on completion of the booklet
 - Patient enters his/her best estimate of height and weight
 - Patient enters his/her best estimate of food eaten in the past year, frequency of eating a food, and portion size
 - Patient not to skip any foods and to mark "NEVER" if did not eat a certain food
- Remain available to answer questions as patient completes the booklet
- Review the completed booklet for completeness and consistency and color in any bubble areas that are partially or lightly completed or go over in #2 pencil any response marked in ink

6.11. Food questionnaire (Block Brief and FQ form)

- Complete the Food Questionnaire Documentation (FQ) form
- Put the completed booklet in a box (or other collection site) at the clinical center to hold for batch mailing to the DCC

Mailing completed questionnaires to the DCC

- Batch mail monthly using a mailing service that tracks packages
- Use the Transmittal Log for Food Questionnaires (TB) as a shipping list for the batch shipment
- Address the batch to:

Food Questionnaire Coordinator
GpCRC Data Coordinating Center
615 North Wolfe Street, Room 5010
Baltimore, MD 21205
410-955-8175

Comments

- The Block Brief food questionnaires are obtained from the DCC; contact Wana Kim (wkim@jhsph.edu) or Pamela Mann (pmann@jhsph.edu) to obtain additional copies
 - The diet analysis provided by the Block group will be sent to the DCC
-

6.12. Rome III Diagnostic Questionnaire (FD form)

Purpose

- To classify patients by the Rome III symptom-based diagnostic criteria

When

- Screening visit b
- Annual follow-up visits (i.e., f048, f096, f144 and f192)

Procedure

- Clinical coordinator should complete Part A of each form and apply labels to subsequent pages as needed before giving the form to patient to complete
 - Self administered, without help from spouse or family
 - Clinical coordinator should check returned forms for completeness before the patient leaves the clinical center. Page 1 should be reattached to pages 2-10 and then the clinical coordinator should complete section B
-

6.13. Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM) (GD form)

What

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

Purpose

- To obtain the patient's views of the severity of his/her gastroparesis symptoms

When

- Screening visit b
- All follow-up visits (i.e., visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192)

Procedure

- Clinical Coordinator should complete Part A of each form and apply labels to subsequent pages as needed before giving the form to the patient to complete
 - Self administered, without help from spouse or family
 - Clinical Coordinator should check returned forms for completeness before the patient leaves the clinical center
-

6.14. Investigator Derived Independent Outcome Measure Scores (IDIOMS) (ID form)

What

- Investigator Derived Independent Outcome Measure Scores (IDIOMS)

Purpose

- To obtain information from the Study Physician regarding the current state of the patient's gastroparesis

When

- Screening visit b
- All follow-up visits (i.e., visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192)

Procedure

- Study Physician completes this form based on the patient's condition since the last screening or follow-up visit

Scoring key

- Severity of Illness Key: Mild symptoms (1-3); Moderate symptoms (4-5); Severe symptoms (6-8); Very severe symptoms (9-10)
 - Other Significant Illnesses: GI organ involvement only and mild other disease (1-3); GI and one other organ system involved and moderate other disease (4-5); GI and 2 other organs system involved, and severe other disease (6-8); GI and 3 or more organ systems involved, and severe other disease (9-10)
 - Intensity of Services Key: Medicines only (1-3); Medicines and home health services (4-5); Medicines, home health services, and 1 inpatient hospitalization in last 12 months (6-8); Medicines, home health services, and multiple inpatient hospitalization in last 12 months (9-10)
-

6.15. Brief Pain Inventory (PI form)

What

- Brief Pain Inventory

Purpose

- To assess the severity and impact on daily functions of the patient's pain.

When

- Screening visit b
- All follow-up visits (i.e., visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192)

Procedure

- Clinical Coordinator should complete Part A of each form and apply labels to subsequent pages as needed before giving the form to the patient to complete
 - Self administered, without help from spouse or family
 - Clinical Coordinator should check returned forms for completeness before the patient leaves the clinical center
-

6.16. State-Trait Anxiety Inventory (Self-Evaluation Questionnaire) (SE form)

What

- Self-Evaluation Questionnaire (STAI)

Purpose

- To collect data on the psychosocial aspects of gastroparesis

When

- Screening visit b
- Annual follow-up visits (i.e., visits f048, f096, f144, and f192)

Procedure

- Clinical Coordinator should complete Part A and apply labels to subsequent pages as needed before giving the form to the patient to complete
 - Self administered, without help from spouse or family
 - Clinical Coordinator should check returned forms for completeness before the patient leaves the clinical center, then complete section B
 - Clinical coordinator must score the questionnaire using the key provided in the form
-

6.17. Beck Depression Inventory (BD form)

What

- Beck Depression Inventory Questionnaire

Purpose

- To collect data on the psychosocial aspects of gastroparesis

When

- Screening visit b
- Annual follow-up visits (i.e., visits f048, f096, f144, and f192)

Procedure

- Clinical Coordinator should complete Part A and apply labels to subsequent pages as needed before giving the questionnaire to the patient to complete
- Self administered
- Clinical Coordinator should check returned questionnaire for completeness before the patient leaves the clinical center, then complete sections B and C
- The score is the sum of 21 items. If the patient has made more than one choice for an item, use the highest scoring item. The maximum total score is 63.

The box below provides guidelines on depression level for patients within certain scoring ranges.

Total Scores	Range
0-13	minimal
14-19	mild
20-28	moderate
29-63	severe

- Special attention should be paid to item 2 and to item 9. Patients admitting to suicide ideation (as measured by item 9) and/or hopelessness (as measured by item 2) with a rating of 2 or 3 should be flagged for further clinical care.
 - Special attention should be paid to item 16 and item 18. Where there are seven answer options (0, 1a, 1b, 2a, 2b, 3a, 3b). If a patient indicates a different answer for either of these questions as compared to when they last completed the form, this should be noted for clinical care.
 - Implement a plan of action per your clinical center's guidelines for caring for patients with:
 - a total score between 29-63;
 - a response of 2 or 3 on item 2 or item 9.
-

6.18. SF-36 Health Survey (QF form)

What

- SF-36 Health Survey (QF) form

Purpose

- To evaluate correlations between self-reported quality of life and disease severity

When

- Screening visit b
- Annual follow-up visits (i.e., visits f048, f096, f144, and f192)

Procedure

- Clinical Coordinator should complete Part A and apply labels to subsequent pages as needed before giving the form to the patient to complete
 - Self administered, without help from spouse or family
 - Clinical Coordinator should check returned form for completeness before the patient leaves the clinical center
-

6.19. Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL) (UG form)

What

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

Purpose

- To evaluate correlations between self-reported quality of life and disease severity

When

- Screening visit b
- All follow-up visits (i.e., visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192)

Procedure

- Clinical Coordinator should complete Part A and apply labels to subsequent pages as needed before giving the form to the patient to complete
 - Self administered, without help from spouse or family
 - Clinical Coordinator should check returned form for completeness before the patient leaves the clinical center
-

6.20. Laboratory Results (LR form)

Who

- All Gastroparesis Registry patients

What

- Form LR covers assessments collected during screening and follow-up:
 - Hematology
 - Liver panel
 - Clinical chemistry
 - HbA1c
 - ANA, Scl-70, CRP, SPEP, Sed rate

When

- All laboratory test results are required at screening visit b
- When laboratory results are available during follow-up
- HbA1c is required at all follow-up visits for diabetic patients

Instructions for form LR

- The measures on form LR are intended to be obtained by chart review, both at screening and during follow-up; the time window for each type of assessment is specified on the form
 - During screening, if the chart review tests are out of the time window or the test conditions can't be ascertained or differ from what is required, the chart review tests cannot be entered on the LR form and the tests should be repeated
 - During follow-up, the time window for the assessment is "in the time window for the follow-up visit (check the patient's Visit time window guide)" – e.g., f048 has an acceptable calendar time period within which it may be done; if you can find a hematology assessment in the patient's chart that was done under the same conditions as required by the study and which provides the required values and was done within the time window for visit f048, you can enter this information on the LR form for visit f048
-

6.21. Plasma and serum collection for Biosample Repository (BP form)

Purpose

- Collection of whole blood from Gastroparesis Registry patients
- Separation of plasma and serum at clinical center: ten - fourteen 0.5 mL aliquots of plasma and ten - fourteen 0.5 mL aliquots of serum are to be obtained in 2.0 mL cryogenic vials
- Store plasma and serum aliquots at -70° C prior to batch shipping to the NIDDK Biosample Repository at Fisher BioServices

Forms / Materials

- BP - Blood Processing for Plasma and Serum
- Labels (MACO) for heparin (green top) tubes and serum separator SST tube (red-gray top)
- Labels for plasma and serum cryovials
- SS - Specimen Shipment log
- NIDDK Biosample Repository shipper

When

- Screening visit at baseline
- Annual follow-up visits (i.e., f048, f096, f144 and f192)
- Batch shipments: Monthly or semi-monthly

By whom

- Phlebotomist
- Clinical Coordinator

Equipment

Blood tubes/aliquot vials

- One 10 mL sodium heparin (green top) tube - *provided by clinical centers*
 - Model/product number: Becton Dickinson product number #367874
 - 100 tubes/pack @ \$41.49
- One 10 mL plastic SST (red-gray top) tube with silica clot activator- *provided by clinical centers*
 - Model/product number: Becton Dickinson product number #367985
 - 100 tubes/pack @ \$24.56
- 28 or more 2.0 mL cryogenic vials - *provided by clinical centers*
 - vials should be able to withstand -196 degrees C
 - vials should be self standing (flat bottom, not curved), externally threaded, 13.5 mm wide x 48.3 mm tall, with silicone washers

6.21. Plasma and serum collection for Biosample Repository (BP form)

- Model/product number: Model #CV200-2
- Vendor contact information:
 - 1) Cryogenic Storage Systems and Supplies
243 Lawyers Road, NW
Vienna, VA 22180
703-319-8247
877-738-8247
703-938-9351 (fax)
 - 2) Corning External Thread Cryogenic Vials
Catalog # 430659
50 per pack, 500pk/case: \$204.17
Telephone: 1-800-492-1110
 - 3) Fisher
1-800-766-7000
Catalog #10-500-26

Labels

- Preprinted labels for whole blood collection tubes (10 mL heparin tube and 10 mL SST tube) and preprinted labels for Form BP – *labels are printed at the clinical center via web-based data management system; use MACO ML-5000 1" x 1 ½" labels, 50 labels/page*
- Preprinted polypropylene labels for 2.0 mL cryogenic vials – *provided by the DCC*

Equipment

- Centrifuge
- -70° C freezer
- Swing out rotor
- 5 mL pipettes
- Barcode scanner (provided by the DCC)

Blood collection and processing procedures

- Patient instructed to fast 8 hours prior to blood draw
- Collect whole blood into one pre-labeled 10 mL heparin (green top; Becton-Dickinson #367874) tube for plasma
- Collect whole blood into one pre-labeled 10 mL SST (red-gray top; Becton-Dickinson #367985) tube for serum
- Blood for plasma and serum to be centrifuged, aliquoted, and frozen within one hour
- If sample appears to have hemolyzed; do not aliquot. Re-draw blood.

Plasma

- Collect blood into heparin (green top; Becton-Dickinson) tube. Ensure that heparin tubes have not expired. (*check that date shown above "Exp" in lower right corner of label is later than current month*)

6.21. Plasma and serum collection for Biosample Repository (BP form)

- Completely fill vacutainer tube
- Mix gently by inversion 5 times
- Within 30 minutes, centrifuge at 1800 x g for 15 minutes at 4° C, preferably with a swing out rotor
- Immediately after centrifugation, insert a 5 mL pipette below surface of plasma
- Remove the clear plasma while avoiding blood cells
- Transfer plasma into aliquots of 0.5 mL each into 10-14 labeled 2.0 mL cryovials
- Freeze at -70° C immediately

Serum

- Collect blood into serum separator (red-gray top) tube. Ensure that SST tubes have not expired. (*check that date shown above “Exp” in lower right corner of label is later than current month*)
- After filling, invert SST tube gently at least 5 times
- Allow blood to clot for **at least 30 minutes** at room temperature
- Centrifuge at 1800 x g for 15 minutes at 4° C, preferably with a swing out rotor
- Transfer 0.5 mL of serum into 10-14 labeled 2.0 mL cryovials
- Freeze at -70° C immediately

Note: Separated serum and plasma may be stored at -20° C for up to one day before transfer to -70° C while ensuring samples remain frozen during the transfer.

Blood Processing for Plasma and Serum (BP) form

- Complete the Blood Processing for Plasma and Serum (BP) form
- Affix labels for the heparin plasma and the SST serum to the BP form
- Affix aliquot 00 cryovial labels to the BP form

Applying labels to cryovials

- Attach the label to the vial when the vial is at room temperature
- Leave the cap on the vial when labeling; the inside of the vial is sterile
- Apply the label to the vial so that the long edge of the label is parallel to the floor when the vial is held in an upright position. The label should not trail off the bottom of the vial or over the cap
- While holding the vial in an upright position, affix the colored portion of the label to the vial first
- Wrap the clear tail around the perimeter of the vial. The end of the clear tail should overlap the colored portion of the label
- Press firmly on the entire label. Verify that all edges of the label adhere to the vial
- When possible, allow newly labeled cryovials to set at room temperature for several hours prior to subjecting them to colder temperatures. (24-48 hours is optimal)

Barcode Scanners

- Plug the scanner to the USB port on your computer
- Open your template Excel file (filename GpCRC_Site61x_shipdate.xls) and replace the x

6.21. Plasma and serum collection for Biosample Repository (BP form)

with the last digit for your clinical center's site ID and replace ship date with the date of shipment

- Place the cursor in the first cell under Barcode number
- Hold the scanner approximately 4-8 inches from the cryovial barcode you wish to scan. (The scanner will emit a red light as it searches for the barcode and will emit a beep and a green dot when the barcode has been successfully read.)
- The scanner automatically enters the barcode into the proper field and immediately goes to the next cell
- Scan all the cryovials you are shipping to the NIDDK Biosample Repository into the Excel spreadsheet
- Place the cryovials back in the freezer or pack in shipper with dry ice to prevent thawing
- For each cryovial barcode scanned, enter the following in the corresponding column of your Excel file: Site ID-Patient ID numbers, the 3 letter patient code, the date the sample was collected (mm/dd/yy format) and the specimen type (S = serum; P = plasma). The volume should be a standard 0.5 and the unit of measure will always be milliliters
- Save the Excel spreadsheet with the correct ship date at the end of the file name (Click on File then click on Save As) and print 2 copies

Packaging Procedures

- Check that 1 absorbent pad is in the Saf T Pack Bio hazard plastic bag
- Insert frozen cryovial into small cardboard boxes with dividers. Place only one tube into each cardboard cell. Each cardboard box may hold 81 cryovials
- Insert each cardboard box with cryovials into its own plastic bag and seal
- Place each plastic bag with specimen box into its own STP-710 Tyvek envelope and seal.
- Place each Tyvek envelope into STP-111 inner brown cardboard box. No more than 3 Tyvek envelopes containing boxes with cryovials can be placed into the STP-111 inner brown cardboard box. If shipping only 1 or 2 specimen boxes, fill the rest of the space inside the cardboard inner box with bubble wrap to prevent movement
- Tape the inner cardboard box closed before placing the styrofoam cooler
- Place cardboard box in upright position in bottom of styrofoam cooler
- Surround the STP-111 inner brown cardboard box with about 8 kg of 2" blocks or nuggets of Dry Ice
- Fill excessive room left in the insulated freezer box with bubble wrap to stabilize specimens in transit
- Place the polystyrene lid onto the freezer box
- Place the "Empty Packaging" cover and shipping form on the top of the cooler lid
- Place a completed Specimen Shipment Log (Form SS) stapled to the Excel spreadsheet of scanned cryovials on top of the cooler lid
- Close and seal outer cardboard box with tape

Labeling Shipper:

- Place a checkmark in the block on the outer cardboard box next to "BIOLOGICAL SUBSTANCE, CATEGORY B". Do not cover this marking with labels.
- Affix a label with your name and return address to the side of the box in the "Shipper:" block

6.21. Plasma and serum collection for Biosample Repository (BP form)

- Affix the repository address label to the side of the box in the “Consignee:” block
- Affix the dry ice label below the repository address label. Enter the weight of dry ice on the label in kilograms
- Affix the “UN3373 BIOLOGICAL SUBSTANCE, CATEGORY B” label to the right of the dry ice label
- Use the preprinted Federal Express air bill to ship specimens to the NIDDK Biosample Repository. Complete return address (leave “Sender Federal Express account number” blank). Section 6, Special Handling: Check “Yes, Shippers Declaration not required,” check “Dry Ice” block and entry “1” x “8”kg. Section 7, Enter “1” under “Total Packages” and the total weight of 24 lbs. Place completed Federal Express Airbill on side of box adjacent to the labeled side. Call Federal Express at 1-800-463-3339; give them the account number in section 7 of the Airbill

Do not write on exterior of box

Do not ship frozen packages on Friday; the repository is closed on weekends

Shipping samples to the NIDDK Biosample Repository

- Specimens are to be batch-shipped monthly to Fisher BioServices on Monday, Tuesday, or Wednesday
 - Aliquots will be stored locally at the clinical center at -70° C prior to shipping
 - Ship specimens in the STP 320 Saf T Pak shipper (provided by the NIDDK Biosample Repository); each shipper can accommodate aliquots for 8 patients, depending on the number of aliquots obtained for each patient (maximum capacity of each shipper is 230 aliquots)
 - Complete the Specimen Shipment Log (Form SS), staple to the corresponding Excel spreadsheet of scanned cryovials and enclose a copy with each shipment of specimens.
 - Keep a notebook of all original completed Specimen Shipment Logs (Form SS) stapled with the corresponding Excel spreadsheet of scanned cryovials so that you have a record of all shipments to the Biosample Repository
 - Email the Excel spreadsheet to the Biosample Repository at bio-niddkrepository@thermofisher.com with the Fed Ex tracking number in the subject line of the email. This email will ensure that you receive a replacement shipper.
 - Notify the Biosample Repository of the shipment via fax (301-515-4049) or email (bio-niddkrepository@thermofisher.com) on the day the package is picked up by Federal Express. Include the tracking number in the notification
-

6.22. Whole blood collection for Genetics Repository (BC, CG and GP forms)

Purpose

- Collection of whole blood from Gastroparesis Registry patients who consent for genetic research
- Shipment of whole blood to the NIDDK Genetics Repository at Rutgers University for DNA banking

Forms

- Gastroparesis Registry consent for genetic research
- Genetic Consent Documentation (CG) form
- Blood Collection for DNA (BC) form
- NIDDK Genetics Initiative Phlebotomy (GP) form

When

- Screening visit at baseline (or any time during follow-up)
- Ship same day as whole blood collection

By whom

- Clinical Coordinator and Study Physician (to obtain consent)
- Phlebotomist (to obtain whole blood)
- Person responsible for shipping whole blood to NIDDK Genetics Repository

Equipment

- Two 10 mL NaEDTA vacutainer tubes (purple top) - *provided by NIDDK Genetics Repository*
- Preprinted whole blood tube labels and form BC labels - *provided by clinical centers (printed from web based data management system; clinical center provides MACO ML-5000 labels (1" x 1 ½ ", 50 labels per page, <http://www.macolabels.com/ml-5000.html>)*
- Shipper - *provided by NIDDK Genetics Repository*
 - One model 470 Thermosafe Safety Mailer (styrofoam body and lid)
 - One 2 ½" x 9" pre-cut section of absorbent materials
 - Two 18" strips of red waterproof tape
 - One press-lock plastic bag
 - One corrugated shipping carton with locking tabs
 - One assembly instructions for Model 472 Thermosafe Safety Mailer

6.22. Whole blood collection for Genetics Repository (BC, CG and GP forms)
Blood collection procedures

- Collect blood into two 10 mL NaEDTA (purple top) tubes
- Invert each tube gently 6 times to mix blood with additives
- Keep blood at room temperature
- Check that patient ID information on preprinted tube labels matches information recorded onto the NIDDK Genetics Initiative Phlebotomy form
- Phlebotomist to sign and date the section: To Be Completed by Phlebotomist on the NIDDK Genetics Initiative Phlebotomy form

Applying labels to tubes

- Attach the label to the tube when the tube is at room temperature
- Leave the cap on the tube when labeling; the inside of the tube is sterile

Packaging procedures

- Ship whole blood at ambient room temperature same day to the NIDDK Genetics Repository
- Package the whole blood tubes in the body of the Safety Mailer (Model 472 Thermosafe Safety Mailer)
- Tear off one section of absorbent materials along perforates and place it so it exactly covers cavity of the Safety Mailer
- Place lid of Safety Mailer over body and absorbent material and press down firmly so that lid closes properly. Reposition absorbent material so that it does not get caught between the lid and body
- Peel backing from two 18" long pieces of red waterproof tape and seal the Safety Mailer lid to the body; peel backing from second piece of tape and continue sealing the mailer, overlapping the first piece of tape about two inches on both ends
- Place the sealed Safety Mailer into the press-lock plastic bag. **Do not seal the bag.**
- Place the NIDDK Genetics Initiative Phlebotomy form in the mailer box outside the plastic bag
- Slide the Safety Mailer and open press-lock bag into the corrugated carton
- Seal the press-lock bag and close carton using the locking tabs
- Place sealing tape (not included) over them

Shipping procedures

- Use the preprinted Federal Express shipping label, marked for *Priority Overnight Delivery*, to ship whole blood to the NIDDK Genetics Repository
- Affix the “UN3373 BIOLOGICAL SUBSTANCE, CATEGORY “B” label to the outside cardboard box
- Call Federal Express, 1-800-Go-FEDEX (1-800-463-3339) for courier. *Due to inconsistent Federal Express delivery around holidays and likelihood of closure of the Genetics Repository on holidays, do not schedule deliveries on the day before or the day of a national holiday. Check with Federal Express and with the Genetics Repository if there is any question about delivery availability or closure.*
- Notify Dana Witt or Elva Peralta at the NIDDK Genetics Repository that blood is being shipped and provide the Federal Express tracking numbers and the NIDDK ID numbers.

6.22. Whole blood collection for Genetics Repository (BC, CG and GP forms)

Notification may be via:

- Web Portal: <http://rucdr.rutgers.edu/shippingblood>
(additional information regarding this portal is at the end of this section)
- Fax: 1-732-445-1149
- Telephone: 1-732-445-1498
- Ship whole blood to:
Rutgers University/Cell Repository/NIDDK
604 Allison Rd., Room C120A
Nelson Laboratory
Piscataway, New Jersey 08854-8000

Genetics Repository Web Portal System

(Rutgers University Cell and DNA Repository - RUCDR)

- Establishing a Username and Password

http://rucdr.rutgers.edu/scripts/up.exe?AIMACTION=vnewaccountconiddk&enforce_color=ON&skey=10925637151082500795

- Go to the URL listed above and then just follow the directions on the top of the page. You can sign up for multiple NIDDK sites (if you are associated with more than one) at once. (Phlebotomists performing off-site draws will send a notice from <http://rucdr.rutgers.edu/shippingblood>.)

Logging in to the System

- The URL for the RUCDR Web Portal is <http://rucdr.rutgers.edu>. Click on the square for NIDDK to get to your login screen. Enter your newly created username and password. If you ever forget your username or password there is an option on this screen to "Retrieve Lost Password". You will need to remember what email address you used to create your account to use this function!

Announcement Board

- When you enter the web portal you will see announcements from the RUCDR. The dates of future holiday closings will be listed here.

Navigating the Web Portal

- Click the tabs on the top of the screen to access the different parts of the web portal. The functions accessible from each tab are listed below.

Request Functions

- From the "Request Functions" tab you can do two things: "Submit Request" or "Look Up Status of Request".

6.22. Whole blood collection for Genetics Repository (BC, CG and GP forms)
1. Submit Request

- To get to these options, pick a function from the drop-down menu: Shipping Blood, Request Mailers, or Question.
- Next, pick a site number from the drop-down menu.
- Fill out the section of the form corresponding with the function you chose. Even if your function choice was not "Question" you can add information to any request in the textbox under the heading "Special Notes/Special Instructions/Questions".
- *Good thing to know! If you choose "Shipping Bloods" you can only enter one FedEx tracking number per submission, but if you have more than one sample in the box you can list all the NIDDK ID numbers separated by commas. As always, do not overpack the mailers and enclose a separate piece of paperwork for each sample.*
- In Section 2: Attachments (a light grey area towards the bottom of the page) you can add a file.

2. Look Up Status of Request

- You can search your recent requests to see their status in multiple ways. These are self-explanatory. If you just hit the search button without selecting any search criteria all the requests you have made will be shown.
- There are 4 different status assignments a request can have:
 - Open
 - Assigned
 - Pending
 - Closed
- **Open:** This status signifies that a request has been submitted, but is not yet assigned.
- **Assigned:** This status signifies that an open request is assigned to a particular staff person.
- **Pending:** This status signifies that a request has been assigned and a staff person is working on it, but hasn't yet completed the job.
- **Closed:** When a request is completed the status is set to closed.

Self Help Resources

- This tab is a holding area for useful documents.
 1. **FAQ** – If you have a question, hopefully it is already answered here.

6.22. Whole blood collection for Genetics Repository (BC, CG and GP forms)

2. **Download Center** – These instructions are here! Also, any paperwork enclosed with mailer kits is here in case you need to print off extras.
3. **View Announcements** – In case you missed the announcement page when you first logged in to the web portal you can read it again.
4. **Support Resources** – Links that may be of interest to visit.

Account Management

- From this tab you can "Modify Your Profile" or "Change Password".

Important Information Regarding Blood Shipments

- When a package is received, a mailer request is filled or a question is answered, you will receive an email from us and the status will be changed to "closed".
-

6.23. Adverse event reporting (IE form)

Definitions

- **Adverse event** is defined as any unfavorable sign, symptom, state, condition, or laboratory finding in a Gastroparesis Registry patient. Adverse events may result from appropriate application of the protocol in relation to the processes of enrolling, studying, or following Gastroparesis Registry participants, as well as from mistake or misadventure.
- **Associated with study participation** means that there is a reasonable possibility that the event may have been caused by participation in the study.
- **Serious adverse event** is defined as any event that suggests a significant hazard, contraindication, side effect, or precaution. Serious adverse event includes any event that is fatal or life-threatening, is permanently disabling, requires or prolongs inpatient hospitalization, or is a congenital anomaly, cancer, or overdose.
- **Unexpected adverse event** is defined as any adverse event that is not identified in nature, severity, or frequency in the risk information included in the Gastroparesis Registry protocol.

Reportable Gastroparesis Registry events

- Any serious and unexpected adverse event thought to be associated with a Gastroparesis Registry procedure is reportable to the Gastroparesis Registry.
- Any event threatening the integrity or well-being of the Gastroparesis Registry (e.g., suspected fraud) is a reportable Gastroparesis Registry event. We recognize that this category is not well-defined; however, it is included as a reminder that reportable events can have a broader scope than events that happen to a patient.
- Deciding whether an event is reportable to the Gastroparesis Registry (i.e., is in either of these categories) will be the responsibility of the Principal Investigator (PI) of the center. The study chair, the NIDDK project officer, and staff at the Data Coordinating Center are available for consultation.

CTCAE v3.0

- Events are reported on the Interim Event (IE) form
- The GpCRC uses the Common Terminology Criteria for Adverse Events, (CTCAE v3.0) to specify and grade adverse events.
- This document is posted on the GpCRC website (www.gpcrc.us – click on Documents)
- Use the CTCAE v3.0 to specify the Short Name for the adverse event and the severity grade for the adverse event.

6.23. Adverse event reporting (IE form)**Local reporting requirements**

- Your institution's IRB has reporting requirements of its own regarding events occurring in the course of conduct of a study. These reporting requirements may be more stringent than those adopted by the Gastroparesis Registry. Regardless of what the Gastroparesis Registry requires, you must continue to meet your local IRB's requirements. If the local requirements are more stringent than the Gastroparesis Registry's, you may report events locally that you do not report to Gastroparesis Registry.
 - Since the Gastroparesis Registry is an observational study, few adverse events related to the study are expected. Potential adverse events are those related to blood draws for the study, such as hematoma, cellulitis, phlebitis, and arterial puncture.
 - If such an event occurs, appropriate medical care should be provided immediately in the clinic.
 - If a suspected adverse event is reported by telephone several days later, the participant should be evaluated in the clinic by medical staff (preferable) or referred to an appropriate facility for evaluation and management.
 - All such events should be documented in the study chart.
-

6.24. Procedures for missed or incomplete visits (MV form)

Purpose

- Record data about missed or incomplete visits

Form

- Missed or Incomplete Visit (MV) form

When

- At close of a visit window for any missed follow-up visit or for any follow-up visit with specific forms not completed

By whom

- Clinical Coordinator

Procedures for missed or incomplete in-person visits

- For a missed visit:
 - Date of missed visit is the last date of the visit window
 - Indicate reason(s) for missed visit
 - For an incomplete visit:
 - Date of incomplete visit is the date on which a partial set of procedures was performed
 - Indicate reason(s) for missed procedures
-

6.25. Procedures for patients lost to follow-up

Purpose

- Ascertain vital status of patient
- Document reason(s) patient did not attend visit
- Ascertain if patient is lost to follow-up

When

- Whenever patient misses a study visit and is difficult to contact

By whom

- Clinical coordinator

Search strategies

- Contact all persons identified on the Patient Location (PL) form
 - Telephone different times during the day/evening
 - Send letter via regular or certified registered mail to determine if patient is still at listed address
 - Check current telephone directory for listings both for the patient and the patient's contacts specified on the PL form, eg., next of kin, health care professionals
 - Check post office for forwarding address; ask patient's contacts for forwarding address
 - Check obituaries
 - Check state vital records
-

6.26. Procedures for mortality closeout

Purpose

- Record participant death

Forms

- Complete the Death Report (DR) form

By whom

- Study Physician and Clinical Coordinator
-

6.27. Medical management of patients (standard of care)

Since the Gastroparesis Registry is an observational study, it will not be the role of study investigators to prescribe or prohibit use of medications as part of the study. Nevertheless, to keep recommendations and care for participants in the study as uniform as possible, investigators should generally discuss with participants what is laid out in the Standards of Care Documents. This can be found in SOP Part IV.

6.28. Screening Contact Log (SL Form)

What

- Screening Contact Log

Purpose

- To record information on patients who are contacted as prospective participants for enrollment in the Gastroparesis Registry

When

- Weekly record prospective participants contacted regarding enrollment

Procedure

- Document your contact with each prospective participant on a single line of the Screening Contact Log (SL) form
 - Each line should be numbered sequentially and the patient identifier may be a name or chart number (this information is not keyed to the data system)
 - Complete items a-k for every prospective participant contacted
 - Number the Screening Contact Log (SL) forms in sequential order
 - Weekly or once you have filled a Screening Contact Log form (10 patients contacted) please key the entire form to the web-based data management system.
 - Key any partial forms during the last week of each month to ensure that your clinical center's recruitment efforts may be summarized accurately in the monthly performance reports
 - Retain the SL forms in your clinical center's GpR files along with other study forms
-

6.29. Gastroparesis Registry Study Closeout (CO form)

Purpose

- To temporarily close out a patient's participation in the Gastroparesis Registry if they are being enrolled into NORIG or another GpCRC main study.

Form

- Closeout (CO) form

When

- The Closeout form should be completed upon enrollment of the GpR patient into another GpCRC study.

By whom:

- Clinical coordinator

Instructions

- Complete and key this form for patients enrolled in the Gastroparesis Registry who are subsequently enrolled in another GpCRC study. All Registry visits will be due until this form is keyed. The keying of this form will turn off the visit windows for the Gastroparesis Registry.
 - If the patient is not enrolled in a new study, this form should not be keyed.
 - If the form has already been keyed, it should be deleted.
-

GpR SOP Part I: Clinical Center Operations

7. Forms management

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7.1. Clinical center ID codes

Alphabetic IDs

- Alphabetic clinic IDs are used on forms, lists, and tables
- Alphabetic clinical center IDs are based on the name of the institution with which the clinical center is affiliated
- Assigned Ids

Kansas Medical Center	KUMC
Stanford University	SU
Temple University	TU
University of Michigan	UMI
University of Mississippi	UMS
Wake Forest University Health Sciences	WFU

- California Pacific Medical Center (CPMC) is a satellite of Stanford University and will use SU's alphabetic and numeric IDs

Numeric site IDs

- The NIDDK Genetics and Biosample Repositories use numeric IDs to identify the GpCRC clinical centers
- These will be used on the specimens (whole blood, plasma, and serum samples sent to the Genetic and Biosample Repositories, respectively)
- Assigned IDs

Kansas Medical Center	637
Stanford University	613
Temple University	610
University of Michigan	611
University of Mississippi	612
Wake Forest University Health Sciences	614
Johns Hopkins University- DCC	61

7.2. Patient identifiers

What

- Patient ID number
- Patient code

Patient ID number

- 4 characters, all numeric
- ID number labels will be distributed to clinics by the Data Coordinating Center
- The ID number for a patient will remain the same for the duration of the GpCRC, even if the patient enters another GpCRC study or if the patient fails screening and is subsequently re-evaluated – the ID never changes

Ranges of patient IDs assigned to clinics

Kansas Medical Center	KUMC	6001	-	6999
Stanford University	SU	4001	-	4999
Temple University	TU	1001	-	1999
University of Michigan	UMI	2001	-	2999
University of Mississippi	UMS	3001	-	3999
Wake Forest University Health Sciences	WFU	5001	-	5999

- California Pacific Medical Center (CPMC) is a satellite of Stanford University and will use SU's range of patient IDs

Patient code

- 3 character alpha code assigned by the Data Coordinating Center and printed on the ID number label
 - Each patient code is unique across the GpCRC
-

7.3. Visit ID code

- 1 to 4 character alpha-numeric code
- Determined by purpose of visit and timing with respect to visit windows
- Visit ID codes

b	Screening, baseline data collection, and enrollment
f016	16 weeks follow-up visit (approximately 4 months)
f032	32 weeks follow-up visit (approximately 8 months)
f048	48 weeks follow-up visit (approximately 1 year)
f064	64 weeks follow-up visit (approximately 1 year, 4 months)
f080	80 weeks follow-up visit (approximately 1 year, 8 months)
f096	96 weeks follow-up visit (approximately 2 years)
f112	112 weeks follow-up visit (approximately 2 years, 4 months)
f128	128 weeks follow-up visit (approximately 2 years, 8 months)
f144	144 weeks follow-up visit (approximately 3 years)
f160	160 weeks follow-up visit (approximately 3 years, 4 months)
f176	176 weeks follow-up visit (approximately 3 years, 8 months)
f192	192 weeks follow-up visit (approximately 4 years)
n	Unscheduled follow-up visit

7.4. General guidelines for forms completion

Ink

- Forms should be completed in ink that is dark enough to photocopy legibly; do not use pencil or colors (e.g., red, green, light blue, or purple) that do not photocopy well

Changing responses on forms

- If an error is made on the form, correct the response by marking through the response with one or two lines and writing the correct response next to or above the original response. The staff member making the correction should put their initials and the date in the margin by the correction. A brief explanation for the change should also be written in the margin; e.g., 'error', 'pt changed mind', 'wrong response checked'.
- Do not obliterate, erase, or white-out incorrect responses
- The idea is to preserve an audit trail of the original response and subsequent changes to it

Multipage forms

- The patient ID number should be written on the top right of every page of every form in the space provided -- protect yourself against ineffective staples and photocopying mishaps

Miscellaneous

- All written responses should be printed legibly so the responses can be keyed to the database
- Do not use abbreviations or short-hand that may not be easily understood or keyed in the written responses
- Numeric data should be recorded in the units prescribed on the form and to the level of precision (number of digits) indicated on the form
- All numbers should be right justified and leading and trailing zeroes should be recorded on the form where applicable (e.g., an age of 8 would be written and keyed as "08").
- All letter codes should be left justified with the remaining spaces left blank (e.g., a visit ID for the screening visit at baseline would be completed and keyed as "b").
- The clinical coordinator should review all responses for completeness and accuracy before signing off on the form
- Wherever possible, forms should be completed in real time, not retroactively. Interviews and questionnaires should be completed on the actual data form.
- The data on some forms, such as the Laboratory Results (LR) form, will be transcribed from worksheets or lab reports, but the visit date on the form should correspond to the date the form was initiated
- Staple relevant lab reports and worksheets to the data form; if your lab reports are transferred to you electronically, print a paper copy of the report and staple the copy to the Database form.

Calculations

- All calculations should be performed using a calculator
- Values should be rounded according to the GpCRC data rounding rule (see section on data rounding rule, later in this chapter of the SOP)

7.5. Instruction box

- Each form includes an instruction box at the top of the first page. This instruction box gives the purpose of the form, when it should be completed, who administers the form, the respondent, and specific instructions for the form
-

7.6. Form skips, stops, caution ineligibility symbols

Skip pattern

- Form navigation (skip pattern) instructions are indicated in **boldface**. Skips are designated by an arrow from that response to a box with the number of the next item to be completed.

Stop sign

- Stops are indicated with an arrow from the response to a stop sign – instructions are given that must be fulfilled in order to continue with the form. For example, Form RG (Registration) asks if the patient has signed the consent form; if the response is “no”, the form is stopped with the instructions that *‘the consent form must be signed prior to continuing with screening’*.



Caution sign

- Items that require further review are indicated with an arrow from the response to a caution sign



Instructions are given regarding completion of the form when a caution is encountered

Ineligibility sign

- Ineligible conditions are designated by an arrow from the response to the symbol:



Other

- Other special instructions are indicated on the form in *italics*. Some examples are:
 - *check only one*: only one of the listed responses should be checked
 - *check all that apply*: one or more of the listed responses may be checked
 - *specify*: a response should be printed on the line(s) provided
-

7.7. Headers and footers

- Each page of each form includes headers and footers which identify the form and the patient. The top right of the first page of each form has a space to check when the form is keyed [()keyed]. The top right of subsequent pages is reserved for the patient ID number. The footers include the form abbreviation, form revision number and date, the form name, and the page number. For example:

Gastroparesis Registry

Patient ID: __ __ __ __

Form RG

Revision 0 (29 Sep 06)

RG - Registration

Page 2 of 3

- The keyed box should be ed when the form is keyed; the person keying the form should also date and initial the form by the keyed box
 - The patient ID number should be written on each page of the form
-

7.8. Key fields

- The first 7 items of each form include the key fields which identify the clinical center, patient, visit and study

A. Clinical center, patient and visit identification

- Center ID: _____
- Patient ID: _____
- Patient code: _____
- Date form completed: ____ - ____ - ____
 day mon year
- Visit code: _____
- Form & revision: _____
- Study: Gastroparesis Registry 1

- The form and revision number will be printed on the forms in item 6; if a form is only used for one specific visit, the visit code will also be printed on the forms
 - When a form revision affects the data that are collected, the form revision number and date will change; if this occurs, older revisions of that form should no longer be used for data collection
 - If the form is revised without affecting the data collection - i.e., the wording of an item is revised - only the revision date of the form will be changed.
-

7.9. Missing data

- If a data item is missing and cannot be obtained when the form is completed or reviewed, write the appropriate code in the first left hand space of the empty data field:
 - ? = data temporarily missing or inconsistent; to be collected or resolved in the near future; items keyed with a ? will need to be followed up on and resolved
 - d = patient does not know the answer
 - n = not applicable in this situation
 - m = data missing
 - r = patient refused
 - When using any of the above codes, the entire data field does not need to be filled with the code (e.g., a missing height would be completed as m _ _ . _).
 - If data are missing on the form, an explanation for the missing values should be written on the form and keyed to the database in the General Comments section of the keying.
 - It is very important to keep the number of missing data items at a minimum, especially at baseline, since many future papers will depend on having a good set of baseline values. If an item is missing at the time the form is filled out, but is expected to be collected in the near future, use a '?' rather than the 'm' code for the item on the form. The 'm' missing code is for items that are truly missing. Coordinators are discouraged from using the 'm' code as a way to get through the data entry checks and enroll a patient; the screening windows should be broad enough to allow you to collect all data within the allotted time window. Also, if the data system will not accept a value because it is out of range, please contact the DCC, so we can make a determination as to whether the range checks need to be adjusted. In the meantime, use a '?' rather than an 'm' on the form. If there is a valid reason that a required baseline laboratory value is missing, please fax the Laboratory Results (LR) form to the DCC along with the reason for the missing value.
-

7.10. Administrative sign off

- Each form contains a section for administrative sign off
 - These items include the Clinical Coordinator PIN and signature and the date the form was reviewed.
 - Depending on the form, they may also include the PIN and signature of other staff
-

7.11. Handling forms

Form duplication

- The individual forms and form sets specific to a particular visit are available on the GpCRC website and on the data system (using the Print task)
- You can print master copies from the website or data system and then photocopy as needed or print as needed from the website or data system – if you print copies ahead of time, do not print huge quantities as forms may be revised, especially in the early days of a study
- If a master copy gets frayed or faded, print a new master — always use clear copies for reproduction masters.

Form storage

- Forms for patients registered but not enrolled in the Gastroparesis Registry should be kept in a single folder in a locked room in a locked filing cabinet.
 - Each patient who is enrolled in the Gastroparesis Registry will have a patient file – either a notebook or file folder which is kept in a locked room or locked filing cabinet. The patient file should contain all Gastroparesis Registry documents for the patient – consents, forms, appointment schedule, labels, randomization materials. The forms should be arranged in the notebook or folder chronologically by visit. Tabs can be used to separate the visits.
-

7.12. Data rounding rules

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 4.73 rounds to 4.7 and 1.44 rounds to 1.4
- 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 4.78 rounds to 4.8 and 4.75 rounds to 4.8

When completing a calculation for the Gastroparesis Registry, apply the rounding rule only at the last step, when required to record a quantity on the Gastroparesis Registry form.

7.13. Data audits and edits

Data audits

- The Data Coordinating Center will serve as the site monitor
- The Data Coordinating Center will conduct periodic data audits as a quality control measure
- Audits may be done by mail or on-site
- During an audit, the forms will be reviewed to see if they were completed and keyed correctly; the forms will also be checked against the source documents to be sure that values were transcribed correctly.

Source documents include but are not limited to:

- Gastric emptying scintigraphy reports
- Upper endoscopy reports
- Gastric imaging study reports
- Laboratory test result reports
- Medical records for archival information
- There are no source documents for questionnaires (the questionnaires are the original documents for the data collection)

Data edits

- Computerized data edits will be sent to the clinics periodically
- The data edits check for consistency and questionable values in the database.

Changes resulting from audits or edits

- Changes made to the forms as a result of an audit or an edit should be marked "per audit" or "per edit" and should be dated and initialed.
-

GpR SOP Part I: Clinical Center Operations**8. Quality assurance**

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8.1. Site visits

Purpose

- Conduct an audit of selected patient data
- Review documentation and procedures for the Gastroparesis Registry
- Tour facilities
- Discuss with clinical center personnel any problems that have occurred or that are expected to occur in conducting the study

The following regulatory and study documents should be available or accessible:

- IRB communications organized with original approval letters, revision approvals, annual renewals, serious adverse event forms, and any communications regarding concerns or special requests from clinical center review board
- Signed and dated consent forms for all participants including the date and signature of a witness
- Documents including Gastroparesis Registry Protocol, PPMs, and SOPs
- Study forms for participants should be available for data audit

Participants

- At least two DCC personnel will attend the site visit. At least one person from another Gastroparesis Registry clinical center will also attend. Representatives from other resource centers associated with the GpCRC may also attend
- GpCRC certified staff from the clinical center

Reviewed during site visit

- IRB documentation
 - Original approval
 - Annual renewals (if applicable)
 - IRB submissions
 - Approval for updated consent forms and protocol
- Gastroparesis Registry Documents
 - Directory
 - SOPs
 - Forms Book
 - PPMs
 - Protocol
- Enrollment and retention
 - Status
 - Recruitment and retention strategies
 - Problems
 - Losses to follow-up

8.1. Site visits

- Personnel
 - Certification status
 - Personnel changes
 - Backup plans for personnel in event of absence

- Clinical management
 - Adverse event reporting procedures
 - Study procedures
 - Clinical center coordination
 - Scheduling
 - Clinical center concerns or problems

- Participant files
 - Security
 - Organization
 - Consent statements
 - Each patient's Gastroparesis Registry forms and their source documents:
 - laboratory test results: clinical chemistries, ANA, Scl-70, HbA1c, CRP SPEP
 - gastric emptying report and scintigraphy on CD
 - upper endoscopy report

- Specimen shipment
 - Comparison of specimens expected and received
 - Shipping procedures and problems
 - Shipping supplies

- Protocol performance
 - Protocol deviations

- Forms and data management
 - Monthly form status reports
 - Source documentation
 - Data audit (selected patients)
 - Eligibility criteria
 - Adverse events
 - Death reports

- Previous site visit report
 - Action items follow-up
 - Data audit follow-up

8.1. Site visits**Site visit follow-up**

- A list of action items is compiled at the end of the site visit to identify items which require further action. The procedure for site visit action item follow-up is:
 - Action items will be listed at the end of the site visit report
 - Clinical centers will be required to respond to action items within 30 days of receipt of the site visit report. Responses should be in writing and sent to the CC.
 - The DCC will be required to respond to the action items within 30 days of the completion of the site visit report. The DCC will send a written report to the clinical center.
-

8.2. Performance monitoring

- The DCC will generate enrollment reports that will provide a count of participants enrolled at each clinical center
 - On approximately a monthly basis, the DCC will generate reports summarizing the performance of all clinical centers. These reports will include information on enrollment and the percentage of expected visits for which documentation has been entered into the Gastroparesis Registry data system. Also, for those visits for which data have been entered, the report will show the percentage of missed visits, the completeness of data collection, the timeliness of data entry, and protocol deviations. Performance reports will be reviewed by the Steering Committee, and the Steering Committee will make decisions regarding actions to be taken in the event that a clinical center is performing poorly.
-

8.3. Data quality surveillance

General procedures

- Quality assurance of data accuracy will occur routinely through three main procedures: data entry checks, monthly checks for completeness and edits, and form audits
- In addition, detection of problems may occur during data analysis. For example, in preparing reports for Steering Committee meetings, problems may be discovered. Outliers and unusual variations or patterns in the data are examined and may reveal problems.
- Quality assurance of data analysis is achieved by independent replication of key analyses within the DCC and review of reports by multiple individuals before distribution

Data entry checks

- The data system will contain checks during the data entry process of range, logic, and consistency of items within forms
- The data system will perform checks between forms to ensure that the same fields entered on different forms match
- A double data entry system will be used for all forms

Monthly check for completeness and edits

- On a monthly basis, DCC will generate a database report of:
 - number of participants enrolled
 - missed visits
 - incomplete visits (missing or pending forms)
 - missed specimen collection or shipment
 - edits (see below)
- Edits are run on the database of the keyed forms monthly. Checks for missing, out-of-range, unusual and inconsistent values, cross-form checks and arithmetic errors are some of the types of checks performed. A listing of edits is sent to each clinical center for resolution. The clinical center must respond to each edit on the listing, make appropriate changes to the forms and database, compute documentation of each change, and file the documentation with the edited data collection form. Items that cannot be corrected (e.g., missing values, unusual measures) are entered into a database at the DCC. These items are excluded from future edits. A hard copy of the edits, with each resolution should be kept in a notebook located at the clinical center.

8.3. Data quality surveillance**Forms audits**

On a periodic (approximately monthly) basis the DCC selects and requests copies of forms for specific participants be sent by each clinical center to the DCC for auditing

- Audited forms are compared with the database; discrepancies are noted and queried
 - Audited paper forms are also inspected for other problems, which are noted and queried
 - Each clinical center will be required to resolve discrepancies from the audit report and fax the resolutions to the DCC within 7 days
 - The DCC will generate a summary report of the audit discrepancies by clinical center to be distributed to all Gastroparesis Registry centers
 - Discrepancy rates over time by clinical center are reported to the Steering Committee
-

GpCRC

*Gastroparesis
Clinical Research Consortium*

**Gastroparesis Registry
Standard Operating Procedures
Part II: Administrative**

4 August 2009

GpR SOP Part II: Administrative

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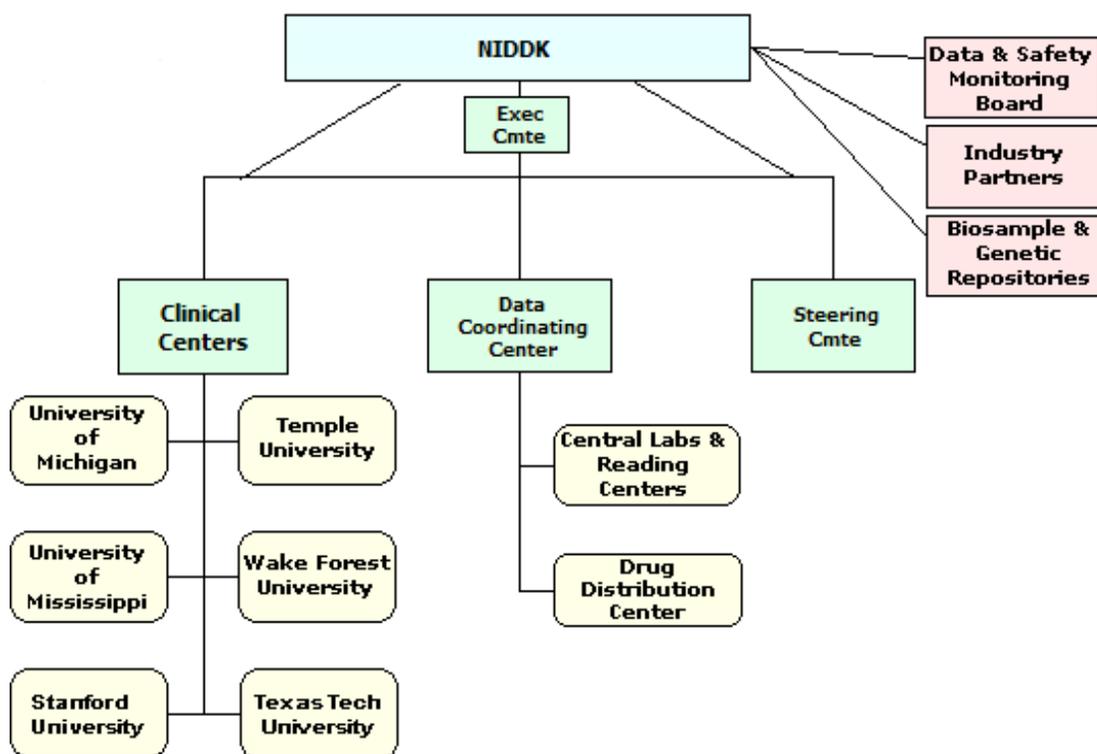
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GpR SOP Part II: Administrative

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1.1. Overview



1.2. NIDDK personnel

Name	Role
Jay Everhart, MD	Advisor
Frank Hamilton, MD, MPH	Project Officer
Stephen James, MD	Advisor
Diana Ly	Budget Officer
Rebekah Sagan, MPH	Executive Secretary to DSMB (alternate)
Rebecca Torrance, RN, MSN	Executive Secretary to DSMB

1.3. Study Chair and Vice Chair

Name	Institution
Pankaj Jay Pasricha, MD	Stanford University
Henry Parkman, MD	Temple University

1.4. Clinical Centers

Clinical Center	Principal Investigator
Stanford University (SU) – California Pacific Medical Center (CPMC)	Pankaj Jay Pasricha, MD William Snape, MD
Temple University (TU)	Henry Parkman, MD
Texas Tech University (TTU)	Richard McCallum, MD
University of Michigan (UMI)	William Hasler, MD
University of Mississippi Medical Center (UMS)	Thomas Abell, MD
Wake Forest University (WFU)	Kenneth Koch, MD

1.5. Data Coordinating Center personnel

Name	Role
James Tonascia, PhD	Director
Aynur Ünalp-Arida, MD, PhD	Deputy Director
Linda Lee, MD	Co-Investigator
Patricia Belt, BS	Project Coordinator
Mika Green, MA	“
Milana Isaacson, BS	“
Wana Kim, BS	“
Laura Miriel, BS	“
Alice Sternberg, ScM	“
Ryan Colvin, MPH	Biostatistician
Michele Donithan, MHS	“
Mark Van Natta, MHS	“
Laura Wilson, ScM	“
Kathie Yates, ScM	“
John Dodge	Forms Development
Jill Meinert	“

Note: The Data Coordinating Center is located in the Johns Hopkins University, Bloomberg School of Public Health, Department of Epidemiology

1.6. Resource Centers

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1.6.1. NIDDK Biosample Repository

Fisher BioServices serves as the Biosample Repository for NIDDK sponsored studies, including the GpCRC studies. Plasma and serum samples will be sent to the NIDDK Biosample Repository at Fisher BioServices for all GpCRC studies (main studies, ancillary studies, or other). Shipping materials for plasma and serum shipment will be provided by the NIDDK Biosample Repository at Fisher BioServices. Specimens that have not been used at the end of NIDDK funding for the study will become available to other researchers, under the supervision of the NIDDK.

Data and samples collected using GpCRC central resources are overseen by the NIDDK; these are GpCRC data and GpCRC samples. Data and samples collected from GpCRC patients under an approved ancillary study protocol and using ancillary study resources are overseen by the ancillary study investigators. Measurements made on GpCRC samples under an approved ancillary study protocol and paid for by ancillary study resources are also overseen by the ancillary study investigators and will be incorporated into the GpCRC database.

Principal Investigator:

Heather Higgins

Contact person:

Sandra Ke

1.6.2. NIDDK Genetics Repository

Rutgers University serves as the Genetics Repository for NIDDK sponsored studies, including the GpCRC. DNA will be banked for future genetics studies in gastroparesis (ancillary studies or other). DNA that has not been used at the end of NIDDK funding for the study and for which study participants gave consent will become available to other researchers, under the supervision of the NIDDK.

Data and samples collected using GpCRC central resources are overseen by the NIDDK; these are GpCRC data and GpCRC samples. Data and samples collected from GpCRC patients under an approved ancillary study protocol and using ancillary study resources are overseen by the ancillary study investigators. Measurements made on GpCRC samples under an approved ancillary study protocol and paid for by ancillary study resources are also overseen by the ancillary study investigators and will be incorporated into the GpCRC database.

Principal Investigator

Jay Tischfield, PhD

Co-investigator and Project Manager

David A Toke, PhD

Director of Communications

Dana Witt

1.6.3. The Mayo Clinic

The Pathological Basis of Gastroparesis (PBG) study is being conducted by the Mayo Clinic located in Rochester, Minnesota under the auspices of the Gastroparesis Clinical Research Consortium (GpCRC). The Mayo Clinic will act as a resource center for the PBG study, which aims to understand the pathological basis of gastroparesis and to identify molecular factors involved in its pathogenesis. The hypothesis is that gastroparesis is associated with identifiable morphological and molecular changes affecting key cellular components regulating gastric motility. The study involves analysis of full thickness biopsies taken from the body of the stomach during gastric surgeries carried out for other reasons. The tissue analyses will be conducted by Dr. Gianrico Farrugia at the Mayo Clinic. Gastric biopsy tissues from approximately 40 individuals with gastroparesis (20 with diabetic gastroparesis and 20 with idiopathic gastroparesis) and gastric tissue obtained as surgical waste from 20 age and sex matched individuals (controls) without gastroparesis will be studied. The GpCRC clinical centers will contribute gastric tissue from 40 individuals with gastroparesis, the Mayo Clinic is responsible for receipt and analysis of stomach tissue biopsies and will provide all the control tissues.

Principal Investigator

Gianrico Farrugia, MD

Contact PersonCheryl Bernard

1.7. Committees

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1.7.1. Steering Committee

- Major decision making body for GpCRC
- Provides oversight in planning and conduct of study
- Votes on all important decisions and approves the final database and protocol and any amendments or modifications of the protocol
- Consists of principal investigators of each of the clinical centers, the principal investigator of the Data Coordinating Center, and the NIDDK Project Officer
- Each member has one vote in any decision requiring formal vote
- Ex officio members include NIDDK scientific staff

Members:

Thomas Abell, UMS
Frank Hamilton, NIDDK
William Hasler, UMI
Kenneth Koch, WFU
Richard W. McCallum, TTU
Henry Parkman (vice-chair), TU
Jay Pasricha (chair), SU
James Tonascia, DCC

1.7.2. Executive Committee

- Manages day-to-day major issues of GpCRC, making decisions in periods between Steering Committee meetings
- Organizes and sets agenda for Steering Committee meetings
- Provides oversight of study
- Consists of GpCRC chair, vice chair, principal investigator of Data Coordinating Center, and NIDDK Project Officer

Members:

Frank Hamilton, NIDDK
Henry Parkman (vice-chair), TU
Jay Pasricha (chair), SU
James Tonascia, DCC

1.8. Data and Safety Monitoring Board

Responsibilities

- To review the research protocols, informed consent documents, and plans for data and safety monitoring, including all proposed revisions
- To evaluate the progress of studies, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the clinical sites, and other factors that can affect study outcome
- To protect the safety of the study participants
- To report on the safety of the study participants and progress of the trial
- To consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study
- To make recommendations to the NIDDK, the Steering Committee, and, if required, to the FDA and IRBs concerning continuation, termination, or other modifications of the studies based on the observed beneficial or adverse effects
- If appropriate, to review interim analyses of efficacy in accordance with outcomes and stopping guidelines, which are clearly defined in advance of data analysis
- To ensure the confidentiality of the study data and results produced for the purposes of interim study monitoring
- To assist the NIDDK by commenting on any problems with study conduct, enrollment, sample size and/or data collection

Membership

- Reza Shaker, MD (Chairperson)
Medical College of Wisconsin
- Patricia A. Cleary, MS
The George Washington University
- Gary Falk, MD
Cleveland Clinic
- Peter A. Gottlieb, MD
Barbara Davis Center, University Colorado Health Science Center
- Anthony Lembo, MD
Beth Israel/Deaconess Medical Center/East Campus

1.8. Data and Safety Monitoring Board**Membership (cont'd)**

- Charlene Prather, MD
St. Louis University School of Medicine
 - William Whitehead, PhD
University of North Carolina, Chapel Hill
-

GpR SOP Part II: Administrative**2. Policies**

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2.1. Conflict of interest disclosure

Policy

- Disclosure of financial relationships with companies or other entities that have interests in gastroparesis research or Gastroparesis Clinical Research Consortium (GpCRC) activities

Purpose

- To avoid potential bias and susceptibility to influence from pharmaceutical companies, biotechnology companies, medical device manufacturers, or other entities whose products or services will be used or tested in the GpCRC, or whose products or services would be directly and predictably affected in a major way by the results of GpCRC studies
- To avoid the appearance of bias or susceptibility

Disclosure procedure

- Statement of relationships with pharmaceutical companies, biotechnology companies, medical device manufacturers, or other entities whose products or services are used, tested, or affected by the GpCRC will be completed
- In general, relationships with a combined level of interest to the investigator, spouse, and dependent children must be disclosed in the following categories:
 - No interest
 - \$10,000 or less or 5% equity or less
 - More than \$10,000 or more than 5% equity
- Initial duality of interest disclosure statements are to be updated annually
- Statement format to be drafted and adopted by the Steering Committee
- Statements will be collected by the Data Coordinating Center or other body appointed by the Steering Committee

Review procedure

- Statements will be summarized by the Data Coordinating Center
- Summaries of collected statements will be reviewed by NIDDK and by the Steering Committee and will be included in Steering Committee meeting books
- Statements will be kept on file at the Data Coordinating Center or other location selected by the Steering Committee

Who must sign a duality of interest disclosure statement

- Principal investigators
- Co-principal investigators
- Investigators who enroll study patients
- Voting members of the Steering Committee
- DSMB members
- Members of standing committees
- Advisors or consultants for the GpCRC

2.1. Conflict of interest disclosure**Examples of interests that must be disclosed**

- Ownership of stock, equity, or other financial interest in any company or entity involved with a GpCRC study (details of the relationship need not be disclosed)
- Employment, office, or directorship in any company or entity involved with the GpCRC
- Personal compensation from any company or entity involved with the GpCRC
- Consulting or advisory arrangements with any company or entity involved with the GpCRC
- Grants, contracts, research, training, or other support from any company or entity involved with the GpCRC
- Travel grants to educational symposia provided by any company or entity involved with the GpCRC
- Intellectual property rights related to the activities of the GpCRC
- Other relationships in which there is or seems to be a dependency relationship between a GpCRC investigator and an entity or company involved in the GpCRC
- Relationship with a company or other entity that may affect academic advancement or status, such as sponsorship of an endowed chair or establishment of a fund for use by the GpCRC investigator

Study duration to which policy applies

- For the duration of GpCRC funding or activity, and beyond that, for up to two years or until all major publications are completed

Possible consequences of a relationship judged to be a conflict of interest with the GpCRC

- No action; disclosure alone is sufficient
 - Relationship is described in a footnote to a paper
 - Investigator is banned from authorship of one or more papers (depends on relationship of conflict to content of paper)
 - Investigator may not vote on any issue related to a company or other entity with which they have a relationship, regardless of the monetary value or nature of the relationship; however, voting rights on such issues may be delegated to a co-investigator, as long as the co-investigator has no relationship with the company or entity
-

2.2. Presentations and publications

Scope

The purpose of the Presentations and Publications Policy is to provide guidance relative to reporting study data and to assure that study reports have expert input, a high standard of scientific quality, responsible conclusions, and sound interpretations and fulfill the overall objectives of the Gastroparesis Clinical Research Consortium (GpCRC).

The presentations and publications policy and procedures apply to original manuscripts (including methodology, validation, laboratory approaches), abstracts, oral and poster presentations, letters to the editor, meeting proceedings, and extended abstracts that include data collected as part of the GPCRC. The policy and procedures also apply to review articles that include original GpCRC data not previously published.

The presentations and publications policy and procedures apply to publications and presentations arising from GpCRC main studies, pilot and feasibility studies, and ancillary studies.

The presentations and publications policy cover the following activities:

- Proposal of manuscripts, review and approval of manuscript proposals, assignment of tasks in analysis and writing, review of manuscripts, authorship policy, and other issues related to publications.
- Proposal of presentations, review and approval or presentation proposals, assignment of tasks in analysis and writing, review of presentations, authorship policy, and other issues related to presentations.
- Make recommendations about topics for publications
- Make recommendations about topics for presentations at national and international meetings
- Make recommendations concerning the priority of manuscripts and presentations
- Review and approval of manuscripts prior to journal submission and review and approval of presentations prior to presentation
- Mediate and settle all disputes and conflicts among study investigators over publication or presentation priorities, authorship, and any other issues related to publications or presentations. Investigators who perceive inequities in authorship or other problems relating to authorship should discuss these concerns with the GpCRC Chair; if the difficulty cannot be settled in this informal manner, the concerned investigator should submit a letter to the Steering Committee outlining the problem. The document will be reviewed and discussed by the Steering Committee, excepting those with a conflict of interest, and a written reply will be made to the investigator.
- Prepare and maintain a list of concepts for publications and prepare and maintain a list of approved GpCRC publications, which shows the status of each manuscript from initiation through publication

2.2. Presentations and publications

The Steering Committee reserves the right to amend the presentations and publications policy and procedures as necessary to clarify their intent.

Goals

- To promote timely, scientifically accurate, and high-quality presentation and publication of findings from GpCRC studies.
- To support broad and equitable participation by GpCRC investigators in presentations and publications.
- To define a set of equitable policy and procedures to determine authorship and the order in which authors are listed.
- To review and select topics for publications and presentations, assign authors to writing groups, set priorities for publications and presentations, and monitor progress of publications and presentations.
- To provide editorial support and timely review for presentations and publications.
- To defend the academic freedom of GpCRC investigators collectively to publish results emanating from the GpCRC studies, while providing limitations on publication of results from any one center that could threaten the integrity of collective data.

Types of publications

- **Main reports** arise from main studies and address the main objectives of main studies or report primary outcome data or design and methods of main studies. Examples of main reports are those that address the efficacy in diabetic, surgical, or idiopathic gastroparesis treatment trials, and design and methods of GpCRC studies.
- **Secondary reports** arise from main studies and address secondary objectives of main studies or report data or design issues or methods that are more peripheral to the main studies than those addressed in main reports.
- **Ancillary study reports** arise from an ancillary study of the GpCRC.
- **Pilot and feasibility reports** arise from a pilot or feasibility study of the GpCRC.
- Abstracts, meeting proceedings, extended abstracts, oral and poster presentations.
- Letters to the editor.
- Press releases.

Writing groups and authorship issues

Writing groups

- **Writing groups:** The writing of manuscripts will be assigned to a writing group consisting of GpCRC investigators, one of whom will be designated Writing Group Chair. Investigators proposing manuscripts may suggest writing group membership and the Steering Committee will approve the writing group chair and members.

Authorship criteria

2.2. Presentations and publications

- Authors should participate in the writing of the paper according to guidelines of the International Committee of Medical Journal Editors (N Engl J Med 1997; 336:309-315). Those who participated in conception and design, analysis and interpretation of data, drafting the manuscript, critical revision of the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors. Expertise (eg, statistical, virology, or pathology) that relates directly to the conduct of the study is additional criterion for authorship. Provision of study material or patients; data collection and assembly; administrative, technical, or logistic support; and obtaining funding do not necessarily merit authorship but should be considered on a case-by-case basis, especially when other contributions are included. Honorary authorship will not be considered.

Authorship format by type of report

- Main reports will have authorship “The GpCRC Research Group”. An appendix listing all investigators in the GpCRC will be included, and the writing group will be designated in a footnote to the title page. The writing group will include one to three clinical center investigators, one investigator from the DCC, and one investigator from the NIDDK.
- Secondary or lesser reports of main GpCRC studies will have modified conventional authorship (Name1, name2, ... and the GpCRC Research Group) or conventional authorship. An appendix listing all investigators in the GpCRC will be included, journal permitting.
- Pilot and feasibility study reports will have modified conventional authorship (Name1, name2, ... and the GpCRC Research Group) or conventional authorship. An appendix listing all investigators in the GpCRC will be included, journal permitting.
- Ancillary study reports will likely have conventional authorship. The GpCRC does not control authorship of ancillary study papers. Ancillary study reports should acknowledge the role of the Steering Committee member who serves as the liaison for the ancillary study but the liaison does not necessarily need to be included as an author unless the Steering Committee member has materially participated in the ancillary study and meets the standard criteria for authorship.

General issues for naming authors

The following points apply when conventional or modified conventional authorship is used for a publication or presentation.

- The writing group, plus any ad hoc contributors who fulfill criteria for authorship, will be listed as authors.
- Order of authorship: The Chair of the writing group will propose authorship order to the Steering Committee based on the level of input into the manuscript. The Steering Committee may amend the order of authorship to recognize an exceptional contribution to the study or the manuscript by an individual. For all manuscripts, factors to be included in decisions about order of authorship are contribution to

2.2. Presentations and publications

- concept, design, and analysis; role in drafting the article or revising it critically for important intellectual content; completeness and integrity of the data and specimens from the investigator's site; and leadership role.
- For journals that limit the number of masthead authors, the following order of authorship will apply until the journal's limit is reached:
 - The writing group.
 - Other investigators identified by the writing group as having made special contributions to the concept, design, or analysis of the study.
 - Other investigators identified by the writing group as having contributed special effort to the execution of the study.
 - If the journal's limit of authors is reached before all writing group members are listed, all others in the writing group will be listed in an Acknowledgments section of the manuscript.
 - Unless he/she delegates otherwise, the Chair of writing group will be the first author.

Proposal of topics and review of proposed topics

- The DCC will keep a list of topics proposed for manuscripts and will maintain a list of approved topics and their status.
- Any member of the Research Group may propose a manuscript. Non Steering Committee members should channel their requests through the Steering Committee member of their site. Proposals must be submitted in writing to the Steering Committee by completion of the Abstract/Publication Proposal (AMP) form which is available on the GpCRC website (www.GpCRC.us). This form requires:
 - a brief description of the background, hypothesis, and purpose of the topic
 - a summary of the analysis plans
 - a description of the subjects to be included
 - a list of variables of interest
 - proposed writing group membership (including statistician) and proposed chair
 - for abstracts, the date of submission and date of the meeting
- The DCC will distribute a copy of the proposals to members of the Steering Committee with a deadline for return of comments (or will schedule a conference call). The Steering Committee members may propose additional or alternate writing group members. The Steering Committee will select the final writing group membership and appoint the writing group chair. The chair will usually be the person who proposed the project.
- Criteria for judging proposals:
 - scientific merit of the hypothesis or aim of the proposal
 - availability of appropriate data to address the hypothesis or aim
- If overlap in content exists between or among proposals, the Steering Committee will either eliminate overlap or consolidate the proposals.

Responsibilities of the writing group

- The chair of the writing group will be responsible for assigning tasks to other members of the writing group and for overseeing the completion of these tasks on schedule.

2.2. Presentations and publications

- Manuscripts will be prepared at the center of the writing group Chair.
- All data analysis will be done through the DCC (mainline papers) or appropriate statistician at a GpCRC site. Based upon their review of these requests, the statistician will provide an estimate of the time and resources required to be included in the final proposal.
- When the manuscript is judged ready for internal review, the chair will submit the completed manuscript to the Steering Committee in care of the DCC.
- If a writing group does not complete its work or fails to meet timeline milestones, the Steering Committee may reassign the roles of chair or select new writing group members. This exigency may be exercised if no draft is produced within 3 months of the availability of a clean data set.
- If, during the course of work on a manuscript, the analysis is found to be too broad for a single manuscript, the writing group may suggest that the data would be more suitable for more than a single manuscript. The writing group must notify the Steering Committee that they plan to narrow the scope of the manuscript.

Acknowledgments to be included in publications and presentations

- All GpCRC manuscripts must include an acknowledgment of NIDDK funding, with specific grant numbers, as well as NIH funding numbers of participating General Clinical Research Centers. Acknowledgment of CRADA partners should be included as well. When appropriate, other institute or center support is to be acknowledged (e.g., National Institute of Child Health and Human Development, National Cancer Institute). Grant numbers do not have to be specified on acknowledgments for abstracts and presentations.
- Ancillary study manuscripts should include an acknowledgment of the Steering Committee member who served as the ancillary study liaison.

Review of manuscripts

- The Steering Committee will serve as the editorial review committee for all manuscripts.
- Manuscripts that are judged ready for review should be submitted to the Steering Committee in care of the DCC.
- The DCC will send all manuscripts received to the Steering Committee for voluntary comment direct to the corresponding author. A deadline for comments will be specified.
- For each report (ancillary study reports are excluded), two Steering Committee members who did not write the paper or two GpCRC Research Group members with relevant expertise will be designated to provide a timely review (within four weeks) of the manuscript for editorial clarity and data integrity. The DCC will simultaneously do their own review of the analysis and statements about the GpCRC protocol. Ancillary study reports will be sent to one Steering Committee member for review for accuracy of statements about the GpCRC resources used in the ancillary study and for appropriate acknowledgment of GpCRC.
- The results of the Steering Committee and DCC reviews will be collated by the DCC and sent to the writing group chair.

2.2. Presentations and publications

- The result of the review may be that the manuscript is approved for submission to NIDDK or that the manuscript needs revision and re-review.
- The final step in the GpCRC review process is submission to NIDDK for review. All papers arising from the GpCRC, including ancillary study reports, must be reviewed by NIDDK prior to journal submission. The writing group chair will submit the manuscript to the NIDDK project officer after receiving approval from the Steering Committee to do so.
- The NIDDK project officer will notify the writing group chair (with a copy to the DCC) when the manuscript is approved for journal submission.
- If a dispute occurs between the authors and the writing group chair, resolution of the dispute is the responsibility of the Steering Committee.
- Although approval by CRADA/CTA partners is not required, as a courtesy, manuscripts that relate to work carried out through the support of a CRADA/CTA will be submitted to the relevant CRADA/CTA partner at the same time as submission to the Steering Committee. CRADA/CTA partners will not have authority to prevent or delay publication. CRADA/CTA partners will be given deadline for return of comments. Their review will occur prior to review by NIDDK.

Publications priorities

- No investigator may jeopardize the publication of GpCRC study results in a peer-reviewed journal by releasing or presenting data prematurely. Local press releases are to be timed to coincide with publication of manuscripts and must respect any applicable publication embargoes.
- No individual site will be permitted to publish site-specific GpCRC results without the approval of the Steering Committee.

Presentations, abstracts, and letters to the editor

- Presentations of GpCRC data at national and international meetings must be approved. The approval process may entail review of slides and printed material by the same mechanism as that used to review abstracts. Steering Committee approval is not required for local presentations and accompanying syllabus material (eg, medical school lectures, continuing education courses, grand rounds lectures, research seminars, etc). Investigators are encouraged to consult the Steering Committee Chair when questions about the propriety of a local presentation arise. If the Chair cannot address such questions readily, the issue will be considered by the entire Steering Committee (via conference call or written communication).
- Presentations and abstracts will generally use modified conventional authorship (name 1, name 2, etc, and the GpCRC Research Group) and will include acknowledgment of NIDDK funding.
- The DCC will be responsible for data analysis and final slide preparation for GpCRC corporate presentations.
- Investigator-initiated abstracts that require data analysis assistance from the DCC must be proposed to the Steering Committee at least 3 months prior to the internal review submission deadline (use the same form used to propose a manuscript). The

2.2. Presentations and publications

Steering Committee will review the proposal, and if approved will prioritize the analysis requests, in consultation with the DCC.

- Completed abstracts are to be submitted to the Steering Committee at least 6 weeks prior to submission to the organization sponsoring the meeting. The abstract will be circulated to the full Steering Committee with a ballot for approval as written, approval with revisions, disapproval, or warrants discussion by the Steering Committee. A majority of the Steering Committee members responding must approve the abstract for it to be approved for submission. Abstracts submitted fewer than 6 weeks prior to the due date will be reviewed in time for submission if possible, but the Steering Committee cannot guarantee to complete the review in time to meet the due date.
- Letters to the editor are to be approved according to the same process as that used for abstracts.

Reprints and postings to the GpCRC website

- Reprints of mainline manuscripts authored by “The GpCRC Research Group” will be purchased by the DCC, and requests for reprints may be addressed to the DCC. Reprints for all other manuscripts are the responsibility of the writing group chair (who may determine that purchase of reprints is not feasible).
- Final versions of GpCRC manuscripts will be posted on the GpCRC website. Slide material prepared for presentation at national or international meetings will also be posted to the GpCRC website.

Acknowledgments:

In drafting the GpCRC Presentations and Publications Policy, we referred to the following sources: Publication and Presentation guidelines of the NASH CRN, Virahep-C, and HALT-C studies sponsored by the NIDDK, and the Presentation and Publication Policy and Procedures of the NETT sponsored by the NHLBI.

2.3. Ancillary studies

1. Background and access to GpCRC specimens or data

The Gastroparesis Clinical Research Consortium (GpCRC) studies comprise well-characterized individuals with diabetic, surgical, and idiopathic gastroparesis. To make the best possible use of this extraordinary resource, the GpCRC encourages external investigators, as well as GpCRC investigators, to develop ancillary study proposals.

Access by ancillary studies to GpCRC specimens or data collected on participants in the ancillary study will be governed by the GpCRC Steering Committee and administered by the Data Coordinating Center. It is likely that access to baseline data from a GpCRC study will be permitted to an ancillary study prior to the conclusion of the GpCRC study, but only after the GpCRC has determined that the baseline data are of a quality suitable for sharing. Follow-up data and information about treatment assignment in a GpCRC clinical trial are unlikely to be available until after the GpCRC trial has ended, regardless of the timing of the ancillary study. Ancillary study investigators should be aware that there may be delays of possibly years before GpCRC data are released.

GpCRC data sets use the GpCRC Patient ID number to link patient records. Ancillary study investigators should request data on the GpCRC participants in their study by providing the GpCRC ID numbers of the patients whose data are requested. The DCC will accept SAS, Excel, Access, ASCII, and other data files of records of GpCRC ID numbers (word processing files are not acceptable, other identifiers are not acceptable). The GpCRC data which have been approved for provision to the ancillary study will be provided in SAS data sets using whatever SAS version is in use at the DCC. Ancillary study investigators should be prepared to deal with SAS data sets.

2. Data sharing

The ancillary study investigator or the GpCRC Steering Committee member serving as the liaison between the GpCRC and the ancillary study are responsible for providing data files including new data (raw or processed) obtained from an ancillary study such as biomarkers measured in GpCRC serum, plasma samples or genomic data generated from GpCRC DNA samples. GpCRC specimens, i.e., serum, plasma, DNA samples, will be provided to the ancillary study investigators under the condition that funding and analytical capabilities are secured to start the ancillary study within three months and, analyses must be completed within six months of receipt of the specimens. Assay results or data obtained from the ancillary study analyses will be made available within one year of completion to the GpCRC for incorporation into the database for use by other investigators. GpCRC clinical information on study participants will be provided to the ancillary study investigator or liaison after all raw or processed data generated through the ancillary study are returned to the GpCRC Data Coordinating Center.

2.3. Ancillary studies

A written progress report must be provided to the GpCRC every six months which outlines data analysis results. A final report outlining study results must be sent to the GpCRC SC at the completion of the project. Any manuscripts resulting from usage of GpCRC specimens must be reviewed by the Steering Committee and GpCRC must receive credit for all presentations and publications resulting from usage of the GpCRC specimens.

Data and samples collected using GpCRC central resources are overseen by the NIDDK; these are GpCRC data and GpCRC samples. Data and samples collected from GpCRC patients under an approved ancillary study protocol and using ancillary study resources are overseen by the ancillary study investigators. Measurements made on GpCRC samples under an approved ancillary study protocol and paid for by ancillary study resources are also overseen by the ancillary study investigators and will be incorporated into the GpCRC database.

3. Definition of ancillary study

An ancillary study is a study that is carried out using GpCRC patients or related materials, but is not a required part of GpCRC activities. Ancillary studies are characterized as requiring new data collection (i.e., additional to that required by the GpCRC). The new data collection might be a new questionnaire for GpCRC patients to complete, a new biologic specimen to obtain from GpCRC patients, or a new measurement on an existing GpCRC specimen. Ancillary studies are also characterized as being outside the specific scientific objectives of the GpCRC studies, sometimes requiring a separate consent form, placing an additional burden on participants, and sometimes funded by a mechanism that is separate from the GpCRC funding mechanisms. An ancillary study may involve all GpCRC patients or GpCRC patients at one or several GpCRC participating centers. An ancillary study is not a statistical analysis of previously collected data.

An ancillary study may not use the central resources of the GpCRC (e.g., Biosample Repository, Genetics Repository, Data Coordinating Center) for ancillary study purposes unless such use is agreed on by the central resource and is supported by funding from the ancillary study. The ancillary study must make its own arrangements for whatever repository, laboratory, data collection, management, and analysis support that it needs.

An ancillary study should not interfere with or duplicate activities of a main study, pilot or feasibility study. Examples of potential GpCRC ancillary studies include proposals on pathobiology or pathophysiology of gastroparesis or collecting new symptoms - or quality of life-related data in the GpCRC population.

2.3. Ancillary studies
4. Implementing an ancillary study

Investigators wishing to conduct an ancillary study must complete an application available at <http://www.jhucct.com/gpcrc/closed/forms/admin/SP.pdf>. The GpCRC Steering Committee will review the application for scientific merit (using the expertise represented by the Committee) and will assess whether the ancillary study represents undue burden for GpCRC patients or could interfere with completion of the GpCRC main study objectives. The GpCRC Steering Committee must approve the ancillary study for it to proceed. Investigators who are responding to a program announcement or applying for funding should gain GpCRC Steering Committee approval for the ancillary study before submitting their application to a funding organization. An ancillary study may be proposed by investigators outside of the GpCRC; however, in that case, a GpCRC Steering Committee member must agree to serve as the liaison between the GpCRC and the ancillary study.

5. Procedure for proposing an ancillary study

An ancillary study is proposed to the GpCRC by submission of a completed Study Proposal (SP) form (<http://www.jhucct.com/gpcrc/closed/forms/admin/SP.pdf>) to the Steering Committee in care of the Data Coordinating Center. This form is available on the closed part of the GpCRC website (www.gpcrc.us). If an external investigator is proposing an ancillary study, he/she can obtain the form through the GpCRC Steering Committee member who will be the liaison for the ancillary study.

Completion of this form will require specification of the following information:

- The principal investigator for the ancillary study and his/her institutional affiliation.
- Names of other key investigators for the ancillary study and their institutional affiliations.
- Name of the GpCRC Steering Committee member who will be the liaison for the study.
- The study title, objective, and estimated start and end dates.
- A concept sheet describing the research design and methods for achieving the proposed study objectives (2 page maximum length - this is to be a concise, well organized description).
- The GpCRC resources which the ancillary study wishes to use:
 - New data or measurements that are to be collected on GpCRC patients or specimens
 - Existing GpCRC data that the study wishes to access
 - Number of patients involved
 - Quantity of specimens to be collected from patients and the conditions of specimen collection
 - If access to previously collected specimens is wanted for new measurements, the quantity and amount of specimens to be used should be specified;
 - Frequency of visits or patient contacts or specimen collection;
 - Types of interview questions or physical measures or data to be collected from patients
 - If access to previously collected GpCRC data is requested (e.g., measures on specimens or patients, treatment information), the nature of the requested data should be described.

2.3. Ancillary studies

- The primary outcome variable and sample size, with justification.
- The funding source and status of funding for the ancillary study; any unreimbursed work or personnel time expected of the GpCRC must be specified so that the Steering Committee can evaluate whether the GpCRC should assume that unreimbursed work or personnel time.
- The status of IRB approval and plans/procedures to protect patient confidentiality.
- An acknowledgment that the GpCRC ancillary studies policy, including the policy on publications and presentations arising from ancillary studies, applies to the ancillary study.

Each ancillary study must have the approval of the Principal Investigator at each GpCRC clinical center which will participate in the study.

The ancillary study activities that use GpCRC resources may not proceed until the GpCRC Steering Committee has approved the ancillary study.

6. Review process for proposed ancillary studies

The Data Coordinating Center will circulate the submitted ancillary study application to the members of the Steering Committee with instructions that they are to send their comments (see below for what they are to comment on) by a specified date. The Data Coordinating Center will assist the Chair to collate the comments and prepare a written memo to the Steering Committee specifying the recommendation for approval or disapproval. The Steering Committee will review that recommendation at their next meeting or conference call and make a decision for approval or disapproval. The principal investigator of the ancillary study and the GpCRC Steering Committee liaison will each receive a copy of the memo directing the Steering Committee to review the study application (so that they know the time frame for review) and a copy of the memo from the Steering Committee specifying the decision for approval or disapproval.

Steering Committee members will be asked to assess:

- Whether the proposed study has sufficient scientific merit.
- Whether the proposed study would interfere with other GpCRC activities.
- Whether the proposed study would hamper continued recruitment or participation in the ongoing or planned GpCRC studies.
- Whether the proposed study is consistent with the GpCRC aim of facilitating a broad range of research.
- Whether they approve/disapprove the proposed study.

7. Publications, abstracts and presentations arising from an ancillary study

Publications arising from ancillary studies do not need to be approved by the GpCRC Steering Committee prior to initiation. However, publications arising from ancillary studies must be reviewed by the GpCRC Steering Committee prior to journal submission; the purpose of the review is to assure

that any statements about the GpCRC study protocol are accurate and that the GpCRC resources used in the ancillary study are appropriately acknowledged. The process for review will be:

- The draft manuscript should be sent to the Steering Committee in care of the Data Coordinating Center; the authors should specify the target journal.
- The paper will be circulated to the Steering Committee for voluntary comment directed to the corresponding author.
- The Chair will identify an internal reviewer for the paper and send the paper to that individual with a deadline for response.
- The reviewer will review the paper for accuracy of statements about the GpCRC resources used in the ancillary study and for appropriate acknowledgment of the GpCRC.
- The reviewer will send his/her review to the Chair.
- The Chair will send a written review to the author.

If a manuscript is not accepted upon initial submission to a journal, the manuscript does not need to be re-reviewed by the GpCRC after revision and prior to resubmission to a journal, unless there have been substantive changes to the statements that relate to GpCRC resources or the acknowledgment of the GpCRC. The Chair will decide if re-review by the GpCRC is needed.

Abstracts and presentations arising from ancillary studies will not require approval from the GpCRC. However, the GpCRC welcomes being informed about such presentations and would provide review of materials if requested. It is expected that any presentation from an ancillary study will include appropriate acknowledgment of the GpCRC resources used by the ancillary study.

Authorship for publications and presentations from ancillary studies is at the discretion of the ancillary study investigators. It is expected that conventional authorship will be used, with an acknowledgment of the GpCRC.

8. Ancillary studies policy and procedures

The ancillary studies policy includes the following:

- To review applications for ancillary studies of the GpCRC and to make recommendations for approval or disapproval
- To maintain a list of all proposed ancillary studies indicating approval status and the liaison. For approved studies, the list will indicate initiation date and the GpCRC centers participating in the ancillary study.
- To maintain a list of allocations or commitments of existing or future GpCRC samples to central GpCRC and to ancillary studies.

The list of all proposed ancillary studies and the list of allocations and commitments of existing or future GpCRC samples will be available on the GpCRC website.

With respect to votes on matters decided by the Steering Committee, each Steering Committee

member has one vote. In case of a tie vote, the Steering Committee will decide by mailed ballot if a meeting or conference call is not needed.

If a Steering Committee member proposes an ancillary study, collaborates on an ancillary study, or is affiliated with the institution of an investigator who proposes an ancillary study, he/she will be excused from reviewing and voting on that ancillary study proposal, similar to NIH peer review policies for avoidance of actual or perceived conflicts of interest.

The Data Coordinating Center supports the ancillary studies operations by arranging conference calls, receiving submitted applications for ancillary studies, administering the process for review of submitted applications, writing correspondence for the Steering Committee, and maintaining the lists of ancillary studies and allocated/committed samples and the document and correspondence files relating the Committee's activities. The Data Coordinating Center relies on the named liaison for each ancillary study and the Steering Committee members in completion of these activities.

8.1. Receipt dates for study proposals

The deadlines for receipt of ancillary study proposals for review by the GpCRC Steering Committee are 1 February, 1 June, and 1 October. Proposals received by 1 February of each year will be reviewed and the proposer notified of the decision by 31 March. Similarly, proposals received by 1 June will be reviewed and the proposer notified by 31 July, and proposals received by 1 October will be reviewed and the proposer notified by 30 November. These receipt dates allow notification of the applicant of the GpCRC Steering Committee's approval or disapproval approximately two months before the NIH due dates for funding applications for new projects.

8.2. Consent and IRB issues

Consent for the ancillary study cannot be part of any GpCRC consent – ancillary studies are separate from the GpCRC by definition. Therefore, each ancillary study must have its own consent form if needed. Each center participating in an ancillary study must have approval from their IRB for participation in the ancillary study. Each center must provide a copy of their initial notice of IRB approval of the ancillary study and a copy of their IRB-approved consent to the Steering Committee prior to initiation of ancillary study activities at the GpCRC center (IRB approval is not required for review of an ancillary study application). Copies of notices of renewal of IRB approval must also be provided to the Steering Committee annually. The DCC will maintain a file of ancillary study IRB approvals and IRB-approved consents.

8.3. Funding issues

Ancillary studies are almost always supported by non GpCRC resources. Investigators proposing ancillary studies should seek funding from outside sources to conduct their research. Examples include funding obtained through investigator-initiated NIH research grant awards (R01s), program announcements, grants from academic institutions, or private sources (e.g., drug companies, non-profit health organizations). The GpCRC Steering Committee can provide letters of support for

applications for funding for ancillary studies approved by the GpCRC. Conduct of ancillary studies must comply with all existing GpCRC and NIH policies and guidelines.

An ancillary study that wishes to use the services of the Data Coordinating Center or any other GpCRC central resource may contact the principal investigator of that resource regarding participation in the ancillary study. Such participation has to be funded with non GpCRC resources.

8.4. Expiration of GpCRC approval

In general, approved ancillary studies must be initiated within one year of being approved, or the approval will be withdrawn; this will allow recycling of resources allocated to an ancillary study that does not go forward, (e.g., due to failure to obtain funding). The principal investigator of the ancillary study and the GpCRC liaison will each receive written notice 2 months before an ancillary study's approval is due to expire. The ancillary study investigator may appeal this expiration of GpCRC approval, e.g., if a funding decision is pending or if an application for funding is being revised and resubmitted. The ancillary study investigator should send a letter requesting an extension of approval to the Steering Committee. The letter should indicate the expected timeline for initiation of the ancillary study and describe the actions that are being taken to meet that timeline.

8.5. GpCRC liaison

An ancillary study that is proposed by an investigator outside of the GpCRC must have a GpCRC liaison. This person must be a GpCRC Steering Committee member. The liaison serves as the communications link between the Steering Committee and the ancillary study. For example, the liaison would provide status reports on the ancillary study as needed at Steering Committee meetings and would assist the Data Coordinating Center as needed in communicating with the ancillary study. The liaison may participate in the ancillary study but participation is not required.

8.6. Changes to an ancillary study's protocol

If a major change occurs to an ancillary study's protocol after it has been approved by the GpCRC (e.g., addition of a visit, addition of a specimen, or addition of a measurement on a GpCRC specimen – something that affects the impact on the GpCRC participant or resource used), the Steering Committee must approve the change before it is implemented.

8.7. Confidentiality

Confidentiality of individually identifiable data about GpCRC participants must be assured. The GpCRC provides no assurances that ancillary studies will be able to identify and contact GpCRC participants in the future, particularly after the GpCRC ends.

Acknowledgments: This policy is based on the ancillary studies policy developed by the NASH CRN; and in drafting the NASH CRN Ancillary Studies Policy, we referred to the following sources:

GpR SOP Part II: Administrative**2. Policies**

Ancillary Studies policies of the Virahep-C, HALT-C, BARC, and CLiC studies sponsored by the NIDDK, and the National Emphysema Treatment Trial sponsored by the NHLBI.

2.4. Dissemination of information

Categories of information about the study

- Information currently in the public domain
- Privileged information (ie, dissemination limited to the study investigators): minutes, meeting materials, draft documents, data reports
- Information disseminated by the participating centers

Release of information

- As the study progresses, information will be released to the public domain, but the release is subject to SC and NIDDK approval

Information about the study may be directed at

- Potential patients
- Medical community referral sources (physicians, gastroenterologists, etc)
- Public relations with the lay community or scientific community
- Scientific community in general

Information directed at potential patients, at referral sources

- Should emphasize the following points:
 - The study represents a collaborative effort involving multiple centers
 - The local center is only one center in the study
 - The study is sponsored by the NIDDK
- Should be limited to efforts to enhance recruitment of patients
- All publicity for recruitment purposes requires IRB approval prior to implementation
- Each clinic should keep a record and copies of local publicity (letters, press releases, flyers, scripts for radio or TV advertisements, etc) for review during site visits or other requests.

Information disseminated at scientific meetings

- This falls under the presentation policy

2.4. Dissemination of information**Strategies for dealing with requests for information**

- Personnel at each center should refer any requests from the news media for information on the study to the principal investigator
 - Any principal investigator asked to supply information on the study at a local level should emphasize the following points:
 - The study represents a collaborative effort involving multiple centers
 - The local center is only one center in the study
 - The study is sponsored by NIDDK
 - Principal investigators should refer all inquiries concerning the study dealing with information not in the public domain to the Study Chair
-

2.5. Availability of data

Data available to study group during the course of the study

- Performance data (e.g., related to recruitment, data management, adherence to protocol, conduct of study procedures)
- Baseline data characterizing the study population
- Limited follow-up data (e.g., gastroparesis exacerbations, treatment strategies) may be discussed with the study group during the course of the study
- During the course of the study, the study operates with a data and safety monitoring board that is responsible for review of accumulating data

Data available to study group upon close of the study

- Follow-up data

Availability of data to public

- Study data of any kind are not available outside the study group until release is approved by the Steering Committee and NIDDK
-

2.6. List of study documents

- Gastroparesis Registry protocol
 - Gastroparesis Registry Forms and Flashcards
 - Gastroparesis Registry consents
 - GpCRC Policy and Procedures Memoranda
 - Gastroparesis Registry Standard Operating Procedures
 - Part I: Clinical Center Operations
 - Part II: Administrative
 - Part III: Web Based Data Management System
 - Part IV: Standard of Care for Patients with Gastroparesis
 - Certificate of Confidentiality
-

GpCRC

*Gastroparesis
Clinical Research Consortium*

Standard Operating Procedures

**Part III: GpCRC Web-Based
Data Management System**

for

**Gastroparesis Registry
NORIG Trial
GLUMIT-DG Study
APRON Trial**

April 2010

SOP III: GpCRC Web-Based Data Management System

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SOP III: GpCRC Web-Based Data Management System

1. Introduction

The major functions of the Gastroparesis Clinical Research Consortium (GpCRC) web-based data management system are:

- Registration of new participants into a study or trial of the GpCRC.
- Data entry of forms.
- Inventory of forms keyed for each participant.
- Eligibility checking and enrollment or randomization.
- Printing blank forms and visit labels,
- Printing listings of visit window schedules, visits due, missing forms, etc.
- Staff training in the functions of the data system using the tutorial system application.
- Certification of data system users via the tutorial system application.

This data system is **not** a replacement of the original data collection forms. Participant data **must** be recorded onto the paper data collection forms before entry of the form data into the electronic database may be done.

Use of the GpCRC data system for purposes other than those described in this manual is prohibited unless permission is received from the Data Coordinating Center (DCC).

The data system is Internet-based. Any computer with Internet Explorer with the settings described in section 2.1 can be used to log into the GpCRC data system and to use any of the system's functions, including data entry of forms.

Security precautions must be taken at all times to protect the integrity of the data system and maintain confidentiality of participant data. For example,

- Verify that the computer's Internet Explorer version and settings are correct before accessing the system.
- Use only the Personnel Identification Number (PIN) assigned to you by the DCC and your authorized password.
- Do not share your password.
- Use precautions so that any forms taken off-site are not lost or shared with outsiders.
- NEVER send any participant identification information to the DCC.
- Always key form data EXACTLY as written on the form.

The system is robust to most problems. Checks have been built in to monitor the integrity of the data (e.g., checks to avoid duplication of data, miskeys of ID information) and to minimize vulnerability of files to damage. You should feel secure in your use of the system, even as you are learning.

If any problems occur while using the data system or if you ever see error messages that you cannot resolve (e.g., data system script errors), leave the system as is, either print the screen with the error or save the image to a file, and e-mail or call the DCC at 410-955-8175 immediately.

SOP III: GpCRC Web-Based Data Management System

2. Getting started

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2.1. Operating System and Internet Explorer requirements

The data system can be accessed from any PC with a Microsoft Windows Operating System and Internet Explorer web browser preferably updated to version 7.0 or higher. The data system functions through the Internet Explorer browser. No other browsers may be used with the GpCRC data system for consistency and security reasons. Before using the system, ensure that the PC's Operating System (OS) and version and settings on Internet Explorer are correct.

1. Establish that there is an Internet connection.
 - Contact your IT department if you do not have an Internet connection.
2. Determine which Operating System is being used.
 - From the desktop, right-click on 'My Computer', then 'System Properties'.
 - The OS and service pack (SP) are given under the General tab.
 - Contact your IT department if you do not have either Microsoft Windows Operating System XP Service Pack 2 or Vista. The data system will function on a windows OS prior to XP, but for reasons of maximum security and consistency, XP or higher is suggested.
3. Determine which Internet Explorer version and service pack (SP) are being used.
 - From the desktop, open Internet Explorer by double clicking on the icon.
 - Click on *Help*, then *About Internet Explorer*.
 - The pop-up window information gives the version and service pack (SP) in use.
4. Download Internet Explorer Version 7 (IEv7) if not previously installed.
 - Go to <http://www.microsoft.com/windows/downloads/default.mspx>.
 - Click on "Download Internet Explorer 7 today" located at top center of page.
 - Follow the instructions to download Internet Explorer 7.
 - Accept all defaults.
 - Restart your PC after installation.
5. Enable Error Notification in Internet Explorer.
 - From the desktop, open Internet Explorer by double clicking on the icon.
 - Click on *Tools*, then *Internet Options*.
 - Select the Advanced tab.
 - Click in the box labeled "*Display a notification about every script error*" located under "Browsing".
 - Click on *Apply*, then *OK*.
6. To access the data system, open the GpCRC website <http://www.jhucct.gpcrc.us> in Internet Explorer and click on *Data System* (at the left side of the home page).

2. Operating system and Internet explorer requirements

7. Set the POP-UP blocker to OFF for the GpCRC website. In Internet Explorer:
 - Click on *Tools*, then *Internet Options*.
 - Select the Privacy tab.
 - Click *Settings* under 'Pop-Up Blocker' at bottom of tab.
 - Type : <http://www.jhucct.gpcrc.us> in space under "Address of Website to allow".
 - Click *Add*, then *Close*, then *Ok*.

 8. **Optional:** Set the GpCRC website as your home page. In Internet Explorer,
 - Click on *Tools*, then *Internet Options*.
 - Select the General tab and type <http://www.jhucct.gpcrc.us> in the address window for the Home page.
 - Click on *OK*.

 9. Most sections of the GpCRC website are password protected. The DCC will periodically change the password and will send an e-mail notification prior to the change. The username is: **gpcrc**. Note that the Data System has a different username and password (section 2.3).
-

2.2. Monthly maintenance

The Internet is a dynamic environment. Personal settings and use of the Internet for non-data entry activities sometimes unintentionally and unknowingly change the Internet Explorer settings. Anti-virus software should be updated and run daily. At least once a month, the following tasks need to be done to help prevent these changes from affecting the GpCRC data system:

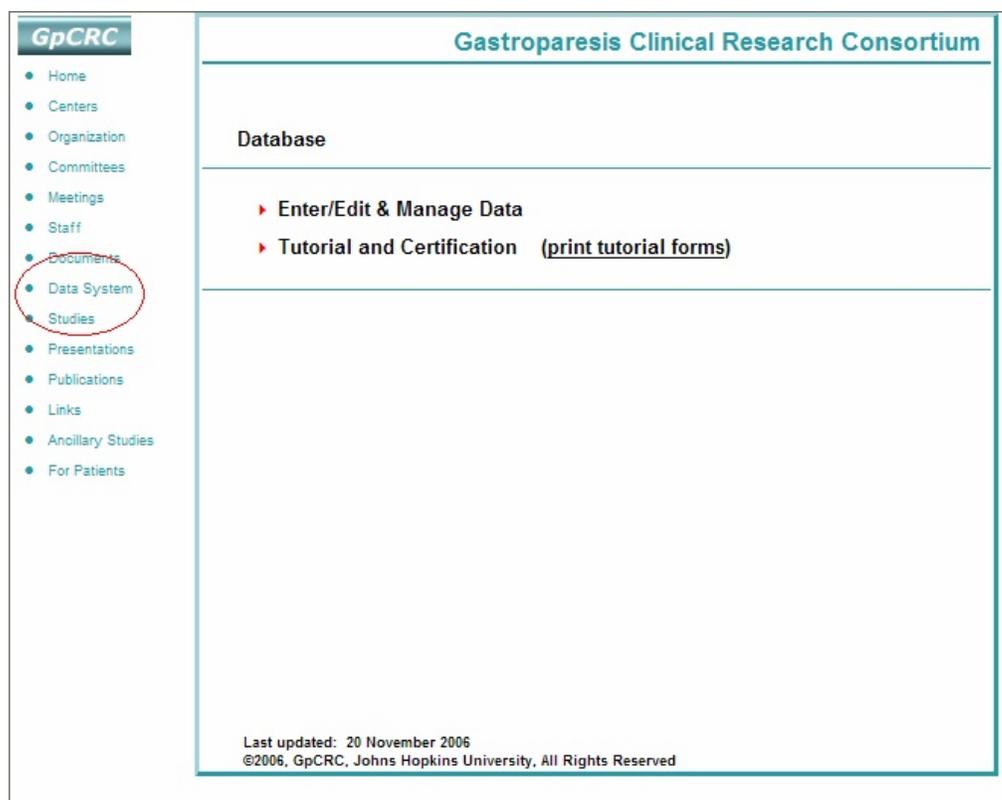
1. Delete temporary Internet files.
 - Open Internet Explorer.
 - Click on *Tools*, then *Internet Options*.
 - Select the General tab.
 - Click on the *Delete* button under Browsing history.
 - Click on the box “*Delete all offline content*” or click on “*Delete files*”.
 - Click on *OK*, then *Close*.
 2. Check enable error notification.
 - Click on *Tools*, then *Internet Options*.
 - Select the Advanced tab.
 - If there is NOT a check in the box labeled “*Display a notification about every script error*” under “Browsing”, then click on the box, then *Apply*, then *OK*.
 3. Verify that the POP-UP blocker is set to OFF for the GpCRC website.
 - Click on *Tools*, then *Internet Options*.
 - Select the Privacy tab.
 - Click *Settings* under “Pop-up Blocker” at bottom of tab.
 - If <http://www.jhucct.gpcrc.us> is not displayed in space under “*Address of Website to allow*,” then key this website address, click on *Add*, then *Close*.
 4. Run anti-virus software.
 5. Run spyware detection software. Freeware such as AD-Aware and SPYBOT can be downloaded from www.download.com.
-

2.3. Log-in procedures

Note that only one person per clinic per study or trial may key forms in the data system at a time, so verify that no other users are logged on working in the same study before beginning your session.

Go to the GpCRC website (www.gpcrc.us) and select *Data System* from the menu on the left to view the Database home page. There are two options. Select either *Enter/Edit & Manage Data* or *Tutorial and Certification* (see figure 2.3a). Until the tutorial has been completed and you become certified for data entry, you will not have access to the first option.

2.3a Database home page and initial log-in (figure)



For either mode, the first thing to appear is the SIGN ON screen (see figure 2.3b). This is a universal log-in for all data system users. Be aware that the username and password are DIFFERENT than those used to access other non-public areas of the GpCRC website (www.gpcrc.us).

2.3. Log-in procedures

- Type in:
Username: **gastrodb**
Password: **nomogp06**
- Click on the *OK* button.

2.3b Data system sign on screen (figure)



The next screen for both the *Enter/Edit & Manage Data* and the *Tutorial and Certification* modes is a personal log-in page (see figure 2.3c). Type in your clinic's ID (see Appendix 11.1) and your unique Personnel Identification Number (PIN) and password.

Every data system user at your clinic must receive a unique PIN from the DCC, define their personal password and become data entry certified. If a clinic staff member has already received a PIN from the DCC (e.g., when becoming certified as a Study Physician or Clinical Coordinator), use this PIN to become data entry certified. Obtaining a PIN and becoming certified is described in Chapter 3 (the tutorial) of this manual.

2.3c Personal log-in (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To begin, type clinic abbreviation (ID),
personnel identifying number (PIN),
and password

Clinic ID

PIN

Password



Messages

Enter clinic name (e.g. umis, tu, wfu)

2.4. Layout description

The TASKS menu screen is the first screen after you are logged into the system for either the data management or tutorial modes. Figure 2.4a shows the MAIN TASKS menu for the *Enter/Edit & Manage Data* mode. It will be used to illustrate several features of the data system. Each screen is comprised of several sections.

- The header contains the Data System name, “GpCRC - Gastroparesis Clinical Research Consortium” and your clinic ID code on the right hand side.
- The middle section of the screen is where you can enter your selections or data. If available for the screen, a help icon will be located on the lower left of the screen. Click on it to obtain more detailed help for that specific screen.
- The bottom section labeled “Messages”, contains a screen description, instructions and when generated, error messages to assist with accurate data entry.

2.4a MAIN TASKS menu screen for Enter/Edit and Manage Data mode (figure)

GpCRC - Gastroparesis Clinical Research Consortium

What do you want to do?

Data Entry >

Screening Log >

Enroll >

Rz Override >

Study Drugs >

Print >

Listings >

Exit



Messages

Select an action

2.4. Layout description

The tasks/actions which can be accessed from the TASKS menu screens are:

- Data entry of forms
- Screening log
- Enroll participants (not available for the tutorial)
- Randomization override (enabled only at the DCC)
- Study drugs (only available for a treatment trial)
- Print option for blank forms and participant labels
- Listings or reports
- Authorize PIN (only available in tutorial)
- Exit system

Select a task by clicking on the button for the task. Many of these tasks bring up additional menus. Each of the tasks on these menus is described later in this manual.

Selection of the *Exit* system option will take you to the desktop. To restart the data system from the desktop, double click on the Internet Explorer icon if the GpCRC data system is your home page, or enter through the GpCRC website.

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3. Tutorial system

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3.1. Introduction

The tutorial system is designed to let you practice data entry for a participant using the forms listed in Appendix 11.2 and to become data entry certified. After completing the tutorial and faxing all requested documentation to the Data Coordinating Center (DCC), you will be certified to enter, edit, and manage your clinic's data using your authorized unique Personnel Identification Number (PIN) and password. Section 3.2 lists all of the steps in the data entry certification process.

Before beginning the tutorial, you must request a PIN from the DCC if you have not already been assigned one, and print the tutorial forms. The tutorial forms are completed with data from an example participant and are ONLY to be used with the tutorial.

To request a PIN from the DCC:

1. Go to the GpCRC website (www.gpcrc.us)
2. Click on *Studies*, then *Gastroparesis Registry*, then *Data forms*, then *Administrative forms* from study of interest (GpR, NORIG, etc.)
3. Print and complete the certification forms, Personnel Certification (PC) and Knowledge Assessment (KA)
4. Fax to the DCC at 410-955-0932
5. The DCC will send you your unique PIN via e-mail.

To print the tutorial forms, either:

- Click on the link given in Appendix 11.2
- From the GpCRC website, click on *Studies*, then *Gastroparesis Registry*, then *tutorial forms* under the SOP III link
- From the database home page, click on *print tutorial forms* (see figure 2.3a)

NOTE that only one person per clinic may do the tutorial at a time. The tutorial and the PIN authorization must be completed before another person may start the tutorial. The tutorial takes an average of 1.5 hours or less to complete.

To use the tutorial, data system:

1. Make sure that no one else from your clinic is keying forms in the tutorial data system.
2. Access the Data System through the Internet Explorer (see section 2.3).
3. Verify that your Internet browser's POP-UP blocker is set to OFF.
4. Click on *Tutorial and Certification*
5. Log-in to the tutorial using username = **gastrodb**, password = **nomogp06**, click *OK* (see figure 2.3b).
6. Log-in to your clinic's site using your Clinic ID (see Appendix 11.1) and your assigned PIN

3.1. Introduction

7. Key your password. The first time you access this screen you will define your own password. Choose a password with 4 to 8 characters that you will remember and do not share it with anyone. Due to security issues, this password should be unique to the individual; define a **different** password from those used for the GpCRC data system or GpCRC website.
8. Click on *Submit*.

The first screen in the tutorial is the tutorial TASKS menu screen (see figure 3.1a) which is similar to the MAIN TASKS menu (figure 2.4a). To data enter forms, browse the data, print labels or tutorial forms, create listings or reports and to run the PIN check, click on the appropriate TASK button. To exit the system and return to the desktop, click on the *Exit* button. The Enroll task is not available in the tutorial.

3.1a Tutorial TASKS menu screen (figure)

TUTORIAL GpCRC - Gastroparesis Consortium Network TU

What do you want to do?

- Data Entry >
- Enroll >
- View Data >
- Print >
- Reports >
- PIN Check >
- Exit

Messages

Select an action

3.1. Introduction

Most of the tasks in the actual GpCRC Data System are available in the tutorial to enable you to practice and become familiar with the capabilities of the data system. This chapter has not been designed to teach you this. Detailed instructions are given in Chapters 4 through 9, and the tutorial directions refer to pertinent sections.

The goal of the tutorial chapter is to inform you of the details of how to become data certified and how to start the process. The data system is very user-friendly, so keying the forms **exactly** as completed and following screen prompts is generally sufficient to complete the tutorial.

Users are highly encouraged to read this manual and explore the various functions, reports and listings available, as a component of the certification process. Also, Appendix 11 includes summary tables of the Data Entry codes and rules and the most frequent Data System Errors and their resolution that can be printed as used as handy references.

The PIN and password that you use for the tutorial will be authorized for data entry and management when you finish the tutorial, run the PIN check, complete the Data Entry Certification/Decertification (DC) form and fax all requested documentation to the DCC. The PIN allows access to the clinic's data system and is used to identify the data entry technician.

3.2. Summary checklist for Data Entry Certification

Below are the steps that must be completed before the DCC will authorize your PIN and password for use of the data system. After you are certified, you may use the GpCRC data system to enter and manage data and create reports for your clinic.

NOTE: Only one person per clinic may do the data system tutorial at a time. Your PIN authorization must be completed before another person may start the tutorial. Plan around 1 hour to complete the tutorial process.

- 1. Review this manual and the GpCRC study's protocol.
- 2. Complete the Personnel Certification (PC) and the Knowledge Assessment (KA) forms and fax to the DCC at 410-955-0932 to request your unique PIN. The DCC will e-mail you your unique PIN. (See section 3.1).
- 3. Download and print tutorial forms (see Appendix 11.2).
- 4. Verify that your internet browser's POP-UP blocker is set to OFF (see Section 2.3). Log-in to the GpCRC tutorial system using your assigned PIN and a 4-8 letter password of your choice.
- 5. Register the example participant by double data entering the tutorial RG1 form (see Section 3.3).
- 6. Print a copy of the RG1 form's confirmation screen (see Figure 3.3d).
- 7. Print the labels for the screening visit b from the *Print* button on the RG1 form confirmation screen (see Section or 3.3).
- 8. Key the rest of the tutorial forms, print a copy of each form's confirmation screen. (See section 3.4).
- 9. Practice browsing and changing data and other tasks available in the tutorial (see Sections 3.4 and 3.5).
- 10. Upon completion of the tutorial, select the *PIN check* option from the tutorial TASKS menu. Resolve any errors, then re-run the PIN check. (See Section 3.6).
- 11. Print the tutorial authorization screen (see Figure 3.6c).

3.2. Summary checklist for Data Entry Certification

- 12. Complete the Data Entry Certification/Decertification (DC) form.
 - 13. Fax copies of the following to the DCC at 410-955-0932:
 - The confirmation screen after data entry of each tutorial form
 - The tutorial authorization screen
 - The completed DC form
 - The screening visit labels generated after registering the example participant
 - 14. Congratulations! You are certified to use the GpCRC data system once you receive the e-mail from the DCC confirming that your PIN is activated for data entry.
-

3.3. Participant registration

After log-in to the tutorial data system, the next step in the tutorial is to register the example participant by keying the tutorial Registration form (RG1). No other forms can be data entered until the RG form is keyed without errors. Detailed directions for the data entry of a form are given in sections 3.4 and 7.1. An outline of the steps to register the example participant are:

1. Click *Data Entry* on the tutorial TASKS menu (see figure 3.1a).
2. Click *Add a data form* (see figure 3.4a).
3. You do not need to key your clinic ID (item 1 on the form). The data system automatically enters your clinic initial's based on the personal log-in data.
4. Key items 2 through 7 (Patient ID = **9521**, Patient code = **xxx**, form date = **15nov06**, visit code = **b**, form+revision code = **rg1**, study number = **1**) twice, then click *Submit*.
5. Type **registry** in the dialog box requesting confirmation of the study and click *OK* (see figure 3.3a below).

3.3a Dialog box to verify study for the tutorial RG1 form (figure)

The screenshot shows a web browser window titled "Data System - Applications - Data Entry - Microsoft Internet Explorer". An "Explorer User Prompt" dialog box is open, displaying the text: "Script Prompt: PLEASE CONFIRM registration into study by typing name of study (registry)". The input field contains "registry". Below the dialog box, the main web page is visible, titled "TUTORIAL" and "GpCRC - Gastroparesis Consortium Network". The page contains a form with the following fields:

Field	Value	Confirm
Patient ID	9521	9521
Patient code	xxx	xxx
Date of form	20nov06	20nov06
Visit	b	b
Form + revision	rg1	rg1
Study	1	1-Registry

At the bottom of the page, there is a "Messages" section with the text: "REGISTRY ADD 1ST KEYING : 9521 xxx b rg1 20nov06 kpy" and "Enter study code".

3.3. Tutorial: Participant enrollment

6. The RG1 data entry screen will be in view as in figure 3.3b.
- Key the response data for the form exactly as written on the form.
 - Completely fill all the spaces in the date fields; Date of birth (item ‘9’ in the “ddmmmyy” format, and other dates in the “ddmmmyy” format)
 - Key a signature as ‘1’

3.3b Tutorial RG data entry screen (figure)

TUTORIAL	GpCRC - Gastroparesis Consortium Network
Registry: Registration Form (rg1)	
1 Clinic ID	tu
2 Patient ID	1200
3 Patient code	otc
4 Visit date	01nov06
5 Visit code	b
6 Form and revision	rg1
7 Study	1
8 Signed informed consent	<input type="checkbox"/>
9 Date of birth	<input type="text"/>
10 Age at last birthday	<input type="text"/>
11 Patient 18 or older	<input type="checkbox"/>
12 Gender	<input type="checkbox"/>
13 Ethnic category	<input type="checkbox"/>
14a American Indian/Alaska Native	<input type="checkbox"/>
14b Asian	<input type="checkbox"/>
14c Black/African American	<input type="checkbox"/>
14d Native Hawaiian/Pacific Islander	<input type="checkbox"/>
14e White	<input type="checkbox"/>
14f Refused	<input type="checkbox"/>
Messages	
REGISTRY ADD 1ST KEYING : 1200 otc b rg1 01nov06 199	
8 Signed informed consent	

7. Press **ENTER** twice once prompted by the pop-up window which appears after keying the last item of the form (see Figure 3.3c).

3.3. Tutorial: Participant enrollment

3.3c Form check after first data entry keying (figure)

The screenshot shows a web browser window titled "GpCRC - Gastroparesis Consortium Network" with "TUTORIAL" on the left and "TU" on the right. The form contains the following fields and values:

8 Signed informed consent	1
9 Date of birth	18aug1970
10 Age at last birthday	36
11 Patient 18 or older	1
12 Gender	2
13 Ethnic category	2
14a American Indian/Alaska Native	
14b Asian	
14c Black/African American	
14d Native Hawaiian/Pacific Islander	
14e White	1
14f Refused	
15 Highest educational level	4
16 Currently employed	1
17 Current occupation	teacher
18 Hours/week work each week	45
19 Missed 2 weeks of work for Gp	2
20 Occupational history category	3
20 Specify other category	
21 Marital status	2
22 Annual household income	4
?? Source of patient	04

A "Messages" section at the bottom of the form displays:

ADD 1ST KEYING : 9521 xxx b rg1 15nov06 kpy
 8 Signed informed consent

A Microsoft Internet Explorer pop-up window is overlaid on the form, containing a yellow warning triangle icon and the text "Press enter twice to check form" with an "OK" button.

8. Correct any data entry errors flagged by the error messages and then click *OK* or press **ENTER** once the next pop-up window is in view (see figure 3.4c).
9. Key the form data again, and resolve any error messages.
10. Click *OK* ONCE to save the form data in the final pop-up window (see figure 3.4d).

Once you have keyed the tutorial Registration form, a screen will appear confirming that you have successfully registered the participant. Print a copy of the confirmation screen (see figure 3.3d).

3.3. Tutorial: Participant enrollment

3.3d Confirmation screen for the tutorial RG form (figure)

TUTORIAL	GpCRC - Gastroparesis Consortium Network
Confirmation	
Confirmation Number: registry-wfu1rg1add-ttt	
Study:	REGISTRY
GpCRC ID:	9521
Patient code:	xxx
Form:	rg1
Visit code:	b
Date of visit:	15nov06
Transaction type:	add
Transaction time:	12/6/2006 9:43:26 AM
Keying rates:	3,497 keystrokes per hour
Verify checks:	2.6 per 100 items
DE oper:	ttt
Click to print Screening labels	<input type="button" value="Print >"/>
	<input type="button" value="Continue >"/>
Messages	
ADD 2ND KEYING : 9521 xxx b rg1 15nov06 ttt	

Print the labels for the participant's screening visit by clicking on the *Print* button next to "*Click here to print Screening labels*" on the Registration form's confirmation screen. For instructions on which labels to use and printing labels, see section 8.2. Briefly, the steps to print the screening visit labels from the confirmation screen are:

1. **Make sure your internet browser's POP-UP blocker is set to OFF**
2. Click on the *Print* button next to "*Click to print Screening labels*"
3. A screen with the participant's labels appears in a PDF file format (see figure 3.3e).
4. Insert one sheet of labels in the printer's single sheet feeder
5. Print the labels using the Adobe PDF PRINT icon or the PDF File/Print menu
6. **Uncheck** the following options when the PDF "Print" confirmation window appears:
 - Shrink oversized pages to paper size
 - Expand small pages to paper size
 - OR Fit to printer margins instead of above 2 options
 - Auto-rotate and center pages

3.4. Data entry

The next step in the tutorial, after keying the registration form (RG), is to key each of the 5 remaining tutorial forms. The process to key each tutorial form is the same as that given in the previous section for the tutorial RG form. A confirmation screen appears after each form is successfully keyed and saved. For the tutorial only, PRINT a copy of each form's confirmation screen which will be faxed to the DCC at the end of the tutorial along with other tutorial materials. When keying data for study participants, it is not necessary to print confirmation screens.

The data system uses **double data entry** which requires that each form's data be entered twice. Though this may seem tedious at first, it is a method that helps to flag many keying and consistency errors BEFORE the data is saved to the electronic database, helping to ensure accurate study data, reducing the number of data audit errors and saving much time in the long run.

NOTE: that data can be saved only for a form keyed twice with no data entry errors. You cannot save your work in the middle of the form.

Click on the *Data entry* task on the tutorial TASKS menu screen (see figure 3.1a). The DATA ENTRY menu screen will appear as in figure 3.4a. The tutorial DATA ENTRY menu is the same as that for the GpCRC data system (see figure 7.1a).

3.4a DATA ENTRY screen (figure)

The screenshot shows a web-based interface for data entry. The top navigation bar includes 'TUTORIAL', 'GpCRC - Gastroparesis Consortium Network', and 'UMI'. The main content area has a heading 'Enter, browse, change, or delete data forms for a patient' followed by four action buttons: 'Add a data form >', 'Browse a data form >', 'Change a data form >', and 'Delete a data form >'. Below these is a '< Previous' button. At the bottom, a 'Messages' section displays 'Data entry' and 'Select an action'.

3.4. Tutorial: Data entry

There are four data entry actions:

- **Add** - to enter new data forms
- **Browse** - to browse previously entered data forms (i.e., look at but do not change)
- **Change** - to change previously entered form data
- **Delete** - to delete previously entered data forms

Clicking on *Previous* returns the system to the tutorial TASKS menu screen.

General guidelines for the keyboard during data entry are:

- Set **Num Lock** on, **Caps Lock** off, **Insert** off
- Use numeric keypad to ENTER numeric data
- Press the **ENTER** key after each item is keyed
- Alternatively, use the scroll bar or mouse and click on the field to be keyed
- Press **Shift+Tab** simultaneously or use the mouse to go back to previously keyed items
- Use the mouse to navigate around the screen

The **Add** task will be used most often in this tutorial; however, as forms are keyed, it is a good idea to practice the other data entry actions to browse, change and delete form data. Each data entry task is described in further detail in Chapter 7.

To enter the data for a new form, click *Add a data form* on the tutorial DATA ENTRY menu. Key items 2 to 7 of the form. These items are called “key” variables and are located in Section A of each data collection form (see figure 3.4b). The key variables uniquely identify the form for a participant, visit and study. Each data item must be keyed twice. After keying this information, hit **ENTER** or click on *Submit*.

3.4b Key variables screen (figure)

TUTORIAL	GpCRC - Gastroparesis Clinical Research Consortium	TU
Enter key information to locate the form in the database.		
Patient ID	<input type="text"/>	Confirm <input type="text"/>
Patient code	<input type="text"/>	<input type="text"/>
Date of form	<input type="text"/>	<input type="text"/>
Visit	<input type="text"/>	<input type="text"/>
Form + revision	<input type="text"/>	<input type="text"/>
Study	<input type="text"/>	<input type="text"/> 1=Registry
<input type="button" value=" < Previous"/> <input type="button" value=" Submit >"/>		
		
<hr/> Messages <hr/>		
ADD: 199		
Enter patient ID		

For all of the tutorial forms, key the following values for the key variables:

- Patient ID - **9521**
- Patient code - **xxx**
- Date of form - date form was completed, which is item 4 on every form
- Visit code - item 5 on every form, either a **b** or an **e**
- Form + revision code - the form code and revision number, e.g., **rg1, lr0**,..., which is item 6 on every form
- Study number - **1** for the Registry study

3.4. Tutorial: Data entry

The form's data entry screen will then be in view as shown in figure 3.3b. **ALWAYS key the data exactly as they appear on the form.** Failure to do so is a serious violation of the integrity of the study.

Data entry rules by type of form item are given in Appendix 11.3. Those used most frequently in the tutorial are:

- Completely fill the data entry space except for special response codes (e.g., m=missing), other or General Comments fields
- Code a '1' if a signature is present
- Key leading and trailing zeroes for numeric responses. **Do NOT key decimal points or commas.**

Once all consistency checks from the first keying are resolved, a pop-up window appears with instructions to press **ENTER** once as in figure 3.4c. The system then saves the responses from the first keying, clears the responses from the data entry screen, and sets the cursor to begin the second keying.

3.4c Clear screen to begin second data entry keying (figure)

The screenshot displays a web browser window titled "GpCRC - Gastroparesis Consortium Network". The page shows a list of data entry fields on the left, including "8 Signed informed consent", "9 Date of birth", "10 Age at last birthday", "11 Patient 18 or older", "12 Gender", "13 Ethnic category", "14a American Indian/Alaska Native", "14b Asian", "14c Black/African American", "14d Native Hawaiian/Pacific Islander", "14e White", "14f Refused", "15 Highest educational level", "16 Currently employed", "17 Current occupation", "18 Hours/week work each week", "19 Missed 2 weeks of work for Gp", "20 Occupational history category", "20 Specify other category", "21 Marital status", "22 Annual household income", and "23 Source of patient". Each field has a corresponding input box. A pop-up dialog box titled "Microsoft Internet Explorer" is overlaid on the screen, containing a yellow warning icon and the text "Press enter to start keying 2" with an "OK" button. At the bottom of the browser window, a "Messages" section shows "ADD 1ST KEYING : 9521 xxx b rg1 15nov06 kpy" and "8 Signed informed consent".

3.4. Tutorial: Data entry

After the last item in the second keying is entered, there is a consistency check between the first and second keying. If the second keying of an item does not agree with the first keying, the cursor will move to the item, and an error message containing the value of the first keying will be displayed at the bottom of the screen. The system saves the second keying, so when correcting the second response keyed, make sure that the corrected value is keyed accurately.

Once all data entry errors have been corrected, click the *OK* button ONCE in the pop-up window shown in figure 3.4d to save the data entry values to the electronic database.

3.4d Save the form data (figure)

Remember that the data entry technician should never change the data on the form to what s/he thinks the response should be.

Errors in the tutorial data entry can be corrected immediately by the technician. The first step is to compare the keyed and recorded form values then verify that the value is in the correct format, that decimal points are not keyed, leading and trailing zeroes are keyed and that skip patterns are followed correctly. Appendix 11.6 lists common data entry errors and their resolution.

KEY OTHER TUTORIAL FORMS OR EXIT DATA ENTRY TASK:

To key another form, select *Data Entry*, then select *Add a new form*, and enter the key fields for the next form to be keyed.

To exit the DATA ENTRY screen and return to the tutorial TASKS menu screen, click on *Previous*, or click on the backward arrow icon on the internet toolbar.

3.5. Additional tutorial TASKS menu functions

Besides the tutorial data entry and PIN check functions described in sections 3.4 and 3.6, respectively, there are additional tasks/functions that can be accessed from the tutorial TASKS menu screen. Though not required for data entry certification, practice using these functions within the tutorial is suggested before managing the clinic's data system. This will familiarize you with the various reports and listings that can be generated through the data system.

The Enroll task is not available in the tutorial. If the *Enroll* button is clicked, the error message, 'Enroll not available in Tutorial', is returned.

VIEWING DATA:

There are two ways to view data; you can browse data (look at but not edit) or you can change data (edit).

To browse the data, click on the *Data Entry* button on the tutorial TASKS menu, then click *Browse a data form* to display a list of forms entered into the data system (see figure 3.5a). The form list can be sorted by Patient ID, visit code or form + revision code by clicking on the SORT order option button. Keying an asterisk (*) for ID, visit, and form + revision displays all of the forms entered in the data system for the specified study (key study = '1' for the tutorial). Clicking on the *Browse* button next to a specific form will bring up that form. A hard copy of lists can be made by clicking on the PRINTER icon in the Internet Explorer menu bar near the top of the screen.

3.5. Additional tutorial TASKS menu functions

3.5a Tutorial Browse data display (figure)

TUTORIAL GpCRC - Gastroparesis Consortium Network

To list forms in the database available for browsing, enter items (or * for all), select SORT options and click "Submit"

To browse a form, click the "Browse" button

Sort by

Patient ID

Visit

Form + revision

Study 1-Registry

Study: REGISTRY

	ID	Patient code	Visit	Form	Date of form	Query
<input type="button" value="Browse"/>	9521	xxx	b	eg1	17NOV06	
<input type="button" value="Browse"/>	9521	xxx	b	lr0	15NOV06	?
<input type="button" value="Browse"/>	9521	xxx	b	rg1	15NOV06	
<input type="button" value="Browse"/>	9521	xxx	b	se0	17NOV06	

Number found: 4

Messages
BROWSE DATA FORM
Enter patient ID or *

There are 2 ways to view form data and also be able to make a change to the data. One is to click on the *View Data* button on the tutorial TASKS menu screen and the other is to click on the *Change a data form* button on the DATA ENTRY menu. Both display a list of forms in the data system that can be edited (see the form list in figure 3.5b). The form list can be sorted by Patient ID, visit code, or form + revision by clicking on the SORT order option button. Keying an asterisk (*) for patient ID, visit, and form + revision for a selected study displays all of the forms in the data system. Clicking on the *Edit* button next to a specific form will bring up that form in change mode after verification of ID, visit, form and study. Hard copies of lists can be made by clicking on the *PRINTER* icon in the Internet Explorer menu bar near the top of the screen.

3.5. Additional tutorial TASKS menu functions

Click on the *Edit* button to display a selected form in CHANGE mode. First, a dialog box requesting confirmation of the GpCRC ID, visit code, form + revision code and study number will pop-up, as in figure 3.5b. Type each item requested separated by commas and click *OK*.

3.5b Dialog box for confirmation of data record to be edited (figure)

The screenshot displays the GpCRC web-based data management system interface. At the top, the page title is "TUTORIAL" and the network name is "GpCRC - Gastroparesis Consortium Network". The user ID is "UMI".

Below the header, there is a section for editing a form. It includes input fields for "Patient ID" (9521), "Visit" (b), "Form + revision" (), and "Study" (1). There are also radio buttons for "Sort by" and a "1=Registry" label. Below these fields are "< Previous" and "Submit >" buttons.

An "Explorer User Prompt" dialog box is overlaid on the screen. The dialog box contains the following text: "Script Prompt: PLEASE CONFIRM: GpCRC ID,visit,form,study (separated by commas)". Below this text is a text input field containing "9521.b,eg1,1". There are "OK" and "Cancel" buttons at the bottom right of the dialog box.

Below the dialog box, there is a table of data records for the "Study: REGISTRY". The table has columns for "ID", "Patient code", "Visit", "Form", "Date of form", and "Query". Each row has an "Edit" button to its left.

ID	Patient code	Visit	Form	Date of form	Query
9521	xxx	b	eg1	17NOV06	
9521	xxx	b	pe0	15NOV06	
9521	xxx	b	lr0	17NOV06	
9521	xxx	b	se0	17NOV06	
9521	xxx	b	rg1	15NOV06	

Below the table, it says "Number found: 5" and there is a "< Previous" button.

At the bottom of the page, there is a "Messages" section and a "VIEW LIST of DATA FORMS" link. Below that, it says "Select an action".

The requested form will be in view and changes can then be made to the data. The data system performs the checks for data entry errors and inconsistencies, and POP-UP windows give prompts for when to submit the form. See section 7.3 for additional instructions.

PRINT TASK:

There are three active print options available from the tutorial print function. Clicking on the *Print* button on the tutorial TASKS menu results in the tutorial PRINT menu screen shown in figure 3.5c. The tutorial **Print Visit windows** option is not enabled. Clicking on the *Previous* button on each print task entry screen returns the system to the tutorial TASKS menu screen.

3.5. Additional tutorial TASKS menu functions

3.5c Tutorial PRINT menu (figure)

TUTORIAL GpCRC - Gastropare

What do you want to view or print?

Visits due >

Blank forms >

Visit windows >

Labels >

< Previous Exit

Messages

Select an action

The tutorial **Print Visits Due** option will display a list of participants with a visit target date in a given month. Click on the *Visits due* button on the tutorial PRINT menu, enter the study (**1** for Registry), month (as 01-12), and year (4 digits) of the target date. The list can be printed by clicking on the PRINT icon. See section 9.12 for further description.

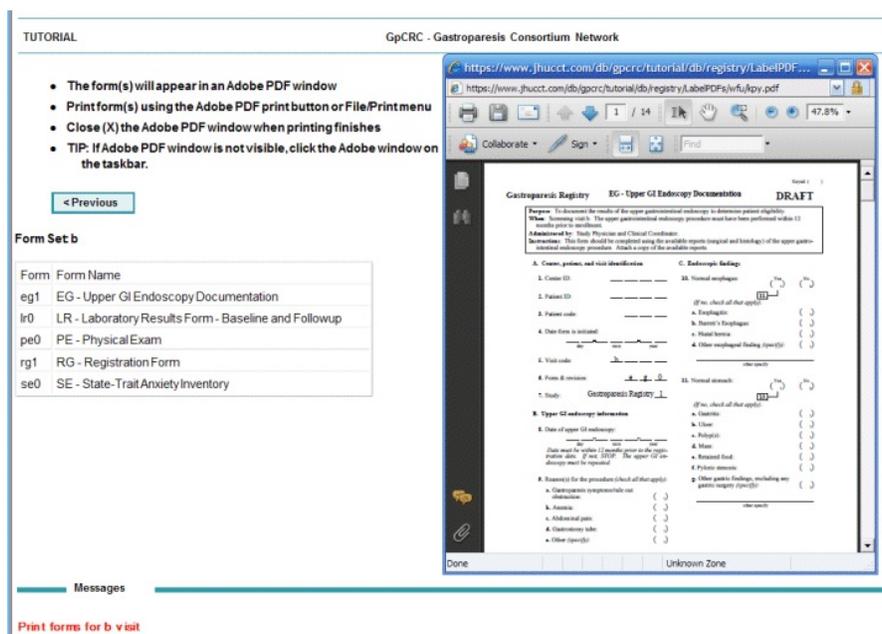
The tutorial **Print Blank Forms** option will display any GpR tutorial form in a PDF file format that can then be printed using the Adobe PDF PRINT icon or File/Print menu. Either a single form (option 1) or a form set for a specific visit (option 2) for the forms used in the tutorial can be printed.

1. Be sure to set your internet browser's POP-UP blocker to OFF.
2. Click on the *Blank forms* button on the tutorial PRINT menu.
3. Key the print option, form or visit code and study number (key study **1** for the tutorial).
4. Click on the *Submit*
5. Note: This option is available in the tutorial only. See section 8.1 for additional information.

3.5. Additional tutorial TASKS menu functions

Figure 3.5d displays the output when printing the form set for all tutorial GpR screening visits. The forms are listed in alphabetical order.

3.5d PDF file output for the GpR tutorial screening visit form set (figure)



The tutorial **Print Labels** option will display a sheet of labels as a PDF file for any Gastroparesis Registry labels that are needed for data collection forms and whole blood collection tubes for a specified follow-up visit. This file can then be printed using the Adobe PRINT icon or File/Print menu. There is one set of labels per participant visit.

1. Be sure to set your internet browser's POP-UP blocker to OFF.
2. Click on the *Labels*, button on the tutorial PRINT menu.
3. Key the patient ID, patient code, visit code, and study number (key study=1 for the tutorial).
4. Click on *Submit*.
5. See figure 3.3e for an example of the PDF label file for the GpR screening visits.
6. See section 8.2 for detailed instructions on printing visit labels.

3.5. Additional tutorial TASKS menu functions

REPORTS or LISTINGS:

There are 3 report options available from the tutorial report task. Clicking on the *Reports* button on the tutorial TASKS menu results in the tutorial REPORTS menu screen shown in figure 3.5e. Clicking on the *Previous* button on each report option's screen returns the system to the tutorial TASKS menu screen. A report can be printed using the PRINTER icon.

3.5e Tutorial REPORTS menu (figure)

TUTORIAL GpCRC - Gastroparesis Co

Select report to view or print

Queries >

Transactions >

Visits done >

< Previous Exit



These 3 reports are only a small subset of the 17 automated report listings available through the GpCRC data system. These are very useful in managing your clinic's data - aiding in report creation, determining which patient visits are due and which data items are still not complete. Section 9 provides detailed directions and screen views for each of the 17 available reports.

The tutorial **Queries** report displays a list of forms with unresolved queries, which are data records containing a question mark (?), which is a special edit code, for the tutorial participant. If a ? was entered for any item on a form, the form is considered incomplete; the ? signifies that the information is temporarily missing. These items must be resolved as data become available.

3.5. Additional tutorial TASKS menu functions

1. Click on the *Queries* button on the tutorial REPORTS menu.
2. Key the Patient ID = **9521**, visit code = **xxx**, form + revision code, and study number = **1**.
3. Click *Submit*.
4. To list all forms with outstanding queries (?) in the data system, key an asterisk (*) for each item except study number (see figure 3.5f).
5. By clicking on the Edit button, the form data will be viewed in CHANGE mode.
6. Section 9.7 gives directions for the similar data system report listing.
7. Appendices 11.4 and 11.5 give additional information about the use of the special query code.

3.5f Tutorial Queries report (figure)

TUTORIAL GpCRC - Gastroparesis Consortium Network

To list forms in the database with queries,
enter items (or * for all), select SORT options
and click "Submit"

To change a form, click the "Edit" button

Patient ID

Visit

Form + revision

Study

Sort by

1=Registry 2=trialxxx 3=trialzzz

Study: REGISTRY

	ID	Patient code	Visit	Form	Date of form	Query
<input style="border: 1px solid black;" type="button" value="Edit"/>	9521	xxx	e	en0	11NOV06	?
<input style="border: 1px solid black;" type="button" value="Edit"/>	9521	xxx	b	eg1	11NOV06	?

Number found: 2

Messages

QUERIES LIST

Enter patient ID or *

3.5. Additional tutorial TASKS menu functions

The tutorial **Transactions** report option displays a summary table of data entry activities for the tutorial participant's forms by the PIN code of the data user who keyed the form for either the current or previous month or the entire study period (see figure 3.5g below).

1. Click on the *Transactions* button on the tutorial REPORT menu.
2. Key the study number (**1** for Registry).
3. Key the activity window option (**1**=this month, **2**=last month, **3**=all).
4. Click on *Submit*.

A report is displayed showing the number of data entry transactions by ADD, CHANGE and DELETE mode for each PIN, and a total number of transactions. See section 9.8 for more details on this report for the GpCRC data system.

3.5g Tutorial Data Entry Transactions report (figure)

TUTORIAL		GpCRC - Gastroparesis Consortium Network	
Transactions by PIN			
Select study:	<input type="text" value="1"/>	1=Registry	2=trialxxx 3=trialzzz
Select display option:	<input type="text" value="3"/>	1=Transactions this month	2=Transactions last month
		3=All transactions	
<input type="button" value=" < Previous"/>		<input type="button" value=" Submit >"/>	
Number of REGISTRY transactions - Total (as of 11/16/2006)			
PIN	Add	Change	Delete
XXX	5	6	0
DCC	1	1	0
Total	6	7	0
<input type="button" value=" < Previous"/>			
Messages			
DE Activity			
Enter study number			

3.5. Additional tutorial TASKS menu functions

The tutorial **Visits Done** report option displays a table of counts of the number of visits completed, visits missed, and the number of forms keyed by visit code (see section 3.5h below).

1. Click on the *Visits done* button on the tutorial REPORT menu.
2. Key the study number (1 for Registry).
3. Click on *Submit*.
4. Section 9.11 gives detailed information for this report for the GpCRC system.

3.5h Tutorial Visits Done (figure)

TUTORIAL		GpCRC - Gastroparesis Consortium Network	
Completed visits			
Select study:			
<input type="text" value="1"/>	1=Registry	2=trialxxx	3=trialzzz
< Previous		Submit >	
Study: REGISTRY			
	Number of visits		
Visit	Completed	Missed	Number of forms
b	1	0	5
e	1	0	1
Total	2	0	6
< Previous			
Messages			
Visit Counts for TU			
Enter study number			

3.6. PIN authorization

Authorization of your PIN and password is the next step in becoming data entry certified, once you have keyed all six tutorial forms.

1. Click on *PIN Check* on the tutorial TASKS menu screen.
2. The PIN authorization page is displayed as in figure 3.6a.
3. Double data enter your Clinic ID (lowercase), PIN, password, name and e-mail address.
4. Click on *Authorize*.

3.6a PIN authorization screen (figure)

TUTORIAL	GpCRC - Gastroparesis Consortium Network																
<p>Check the tutorial and authorize a new PIN for the data system</p> 	<table border="0"> <tr> <td></td> <td style="text-align: center;">Confirm</td> </tr> <tr> <td>Clinic</td> <td><input type="text"/></td> </tr> <tr> <td>PIN</td> <td><input type="text"/></td> </tr> <tr> <td>Password</td> <td><input type="text"/></td> </tr> <tr> <td>First name</td> <td><input type="text"/></td> </tr> <tr> <td>Last name</td> <td><input type="text"/></td> </tr> <tr> <td>e-mail address</td> <td><input type="text"/></td> </tr> <tr> <td>e-mail confirm</td> <td><input type="text"/></td> </tr> </table>		Confirm	Clinic	<input type="text"/>	PIN	<input type="text"/>	Password	<input type="text"/>	First name	<input type="text"/>	Last name	<input type="text"/>	e-mail address	<input type="text"/>	e-mail confirm	<input type="text"/>
	Confirm																
Clinic	<input type="text"/>																
PIN	<input type="text"/>																
Password	<input type="text"/>																
First name	<input type="text"/>																
Last name	<input type="text"/>																
e-mail address	<input type="text"/>																
e-mail confirm	<input type="text"/>																
	<input type="button" value=" < Back"/> <input type="button" value=" Authorize"/>																
<hr/> <p style="text-align: center;">Messages</p> <p>Tutorial: PIN AUTHORIZATION</p> <p>Enter Clinic</p>																	

The tutorial will be checked for completeness by the data system.

If the tutorial is incomplete, error messages will be displayed as in figure 3.6b. All errors must be resolved, and the PIN check option re-run until there are no error messages.

3.6b Tutorial incomplete (figure)

TUTORIAL GpCRC - Gastroparesis Consortium Network

Tutorial incomplete -- PIN not authorized
The following forms were not entered by xxx: se0 pe0 eg1 lr0 en0

Check the tutorial and authorize a new PIN for the data system

	Clinic	Confirm
Clinic	<input type="text" value="..."/>	<input type="text" value="wfu"/>
PIN	<input type="text" value="..."/>	<input type="text" value="xxx"/>
Password	<input type="text" value="..."/>	<input type="text" value="..."/>
First name	<input type="text" value="bal"/>	
Last name	<input type="text" value="timore"/>	
e-mail address	<input type="text" value="bmore@gmail.com"/>	
e-mail confirm	<input type="text" value="bmore@gmail.com"/>	

Messages

Tutorial: PIN AUTHORIZATION
Enter Clinic

Once all the checks are passed, an e-mail will be sent to you and to the DCC containing your PIN and password and the system will display the Tutorial Authorization screen (see figure 3.6c). **Print** the Tutorial Authorization screen.

3.6. PIN authorization

3.6c Tutorial authorization screen (figure)

TUTORIAL	GpCRC - Gastroparesis Consortium Network
----------	--

Tutorial: Authorization of PIN for Data Entry

Authorization Number: tu-xxx-11/16/2006 11:33:43 AM

Clinic:	TU
PIN:	xxx
Name:	mary land
e-Mail address:	mland@gmail.com

Transaction type:	PIN Authorization
Transaction time:	Thu Nov 16 11:33:42 EST 2006

[Continue](#)

Messages

Authorization complete

Go to the GpCRC website, click on *Studies*, then *Gastroparesis Registry*, then *Data Forms*, then *Administrative forms*. Print and complete the Data Entry Certification/Decertification (DC) form.

Fax copies of the following to the DCC at 410-955-0932:

- The confirmation screen after data entry of each tutorial form
- The tutorial authorization screen
- The completed DC form
- The screening visit labels generated after registering the example participant.

After review of your materials and forms, the DCC will activate your PIN and password for data entry. You will receive an e-mail confirming that your PIN is activated for data entry.

SOP III: GpCRC Web-Based Data Management System

4. Participant screening and registration

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4.1. Screening log of potential participants

The Screening Contact Log is designed to record information on patients who are contacted as prospective participants for enrollment in the GLUMIT-DG study or NORIG or APRON trials. Each clinical center should document their contact with each prospective participant on a single line of the Screening Contact Log (SL) form. Each line should be numbered sequentially and the patient identifier may be a name or chart number (this information is not keyed to the data system). Complete items a-k for every prospective participant contacted. Number the Screening Contact Log (SL) forms in sequential order.

Once you have filled a Screening Contact Log form please key the entire form to the web-based data management system. Key any partial forms prior to the 15th of each month to ensure that your clinical center's recruitment efforts may be summarized accurately in the monthly performance reports.

To data enter the SL form:

1. Log-in to the GpCRC data system (see section 2.3)
2. Click *Screening Log* on the MAIN TASKS menu
3. Click *Add an entry* on the SCREENING LOG menu (see figure 4.1a)
4. Double data enter the SL item a (the next sequential 3-digit ID number); the form + revision code = **sl1**, study number (e.g., **2** for NORIG, **3** GLUMIT-DG, **4** for APRON)
5. Click *Submit*
6. Key the remaining SL form items c-k.
7. Click *Save*

Retain the SL forms in your clinical center's study (e.g., GLUMIT-DG, NORIG) files along with other study forms.

4.1. Screening log of potential participants

4.1a SCREENING LOG menu

GpCRC - Gastroparesis Cli

Add, browse, or change an entry in the Registry Screening Log

Add an entry >

Browse an entry >

Change an entry >

< Previous



Messages

Data entry

Select an action

To browse the forms in the Screening Contact log, click on *Browse an entry* on the SCREENING LOG menu, key the study number for a specified study and click *Submit*. All forms in the screening log for the selected study will be displayed (see figure 4.1b). The PRINT icon on the browser menu bar may be used to print a hard-copy of the list. To return to the SCREENING LOG menu, click the *Previous* button at the end of the form list.

4.1. Screening log of potential participants

4.1b Browse the Screening Contact log forms

GpCRC - Gastroparesis Clinical Research Consortium

To browse forms in the screening log, select the study and click "Submit"

Study 1=Registry

< Previous Submit >



**Study: REGISTRY
Screening Log**

Sequence number	Form	Date of form	Query	Age	Sex	Ethnicity	Race	Source	How Contacted	Register	Reason not registered
001	sl1	22jun07		34	F	2	5	1	2	Y	
002	sl1	14aug07		49	F	2	5	1	2	Y	
003	sl1	21aug07		25	M	2	5	1	2	Y	
004	sl1	19jun07		53	F	2	4	2	2	Y	
005	sl1	28aug07		42	F	2	5	2	2	Y	
006	sl1	11sep07		56	F	2	4	2	2	N	6
007	sl1	04sep07		77	M	2	5	1	2	Y	
---	--	--	--	--	--	--	--	--	--	--	

Messages

BROWSE SCREENING LOG

To change a form's information:

1. Click on *Change an entry* on the SCREENING LOG menu
2. Key the specified form's 3-digit Sequence number, form + revision code and study number
3. Click on *Submit* to display the form in the EDIT mode (see figure 4.1c)
4. Click on the *EDIT* button
5. Key the Sequence number, form and study code separated by commas in the script dialog box
6. Click *OK* to display the form's data
7. Key the data edits
8. Click on the *Save* button

4.1. Screening log of potential participants

4.1c Edit a Screening Contact log form

GpCRC - Gastroparesis Clinical Research Consor

To list entries in the screening log available for change, enter items (or * for all), select SORT options and click "Submit"

To change a screening log entry, click the "Edit" button

Sort by

Sequence

Form + revision

Study 1=Registry



Study: Registry
Screening Log

	Sequence number	Form	Date of form	Query
<input style="border: 1px solid #0070C0;" type="button" value="Edit"/>	001	sl1	22jun07	

Messages

EDIT SCREENING LOG ENTRY

4.2. Registration of participants

Before any data may be recorded or keyed for a participant, the participant must give HIPAA authorization and consent to screening for the GpCRC study or trial. The next step is to print the forms needed to register and screen the patient. Briefly,

- The form set should be printed from the GpCRC website by clicking on *Studies* from the left-hand menu, the selected study link, *Data forms*, and then select *Baseline visit (b)*, or *Screening forms* under the corresponding form set. This form-set will be ordered by whether the form is self-administered or completed by the clinic coordinator.

The participant is registered in the data system by completing and keying the Registration (RG) form. Registration establishes the participant's study identifiers (patient ID number and patient code) in the electronic database.

To data enter the RG form for a participant:

- Ensure that your Internet Explorer browser POP-UP blocker is turned OFF
- Log-in to the GpCRC data system (see section 2.3)
- Click *Enter/Edit & Manage Data*
- Click *Data Entry* on the MAIN TASKS menu (see figure 2.4a)
- Click *Add a data form* (see figures 3.4a and 7.1a)
- Key the RG form for the participant exactly as it is coded
- Type the study name (e.g., registry, norig, glumit or apron) (see figure 4.2a) in the POP-UP window requesting confirmation of the study after the key variable items (items 2 through 7) are keyed.

4.2. Registration process

4.2a Dialog box to verify study for the RG form (figure)

The screenshot shows a Microsoft Internet Explorer window titled "Data System - Applications - Data Entry - Microsoft Internet Explorer". An "Explorer User Prompt" dialog box is open, displaying the following text:

Script Prompt:
PLEASE CONFIRM registration into study by typing name of study (registry)

The dialog box has "OK" and "Cancel" buttons. Below the dialog box, the main web page is visible, titled "GpCRC - Gastroparesis Consortium Network" and "TU". The page contains a form for entering key information to locate the form in the database. The form has the following fields:

	Confirm
Patient ID	9521
Patient code	xxx
Date of form	20nov06
Visit	b
Form + revision	rg1
Study	1

At the bottom of the form, there are buttons for "< Previous" and "Submit >". A message bar at the bottom of the browser window displays the following text:

Messages
REGISTRY ADD 1ST KEYING : 9521 xxx b rg1 20nov06 kpy
Enter study code

The data system requires that the responses be keyed twice and pass all edit checks before the form data will become part of the database. After saving the form data, a confirmation screen will be in view as in figure 4.2b. The date by which enrollment must be completed is given. Screening visit labels can be printed by clicking on the *Print* button. Detailed directions for the data entry of forms are given in chapter 7.

4.2. Registration process

4.2b Confirmation screen (figure)

GpCRC - Gastroparesis Consortium Network	
Confirmation	
Confirmation Number: registry-tu3rg1add-lam	
Study:	REGISTRY
GpCRC ID:	1003
Patient code:	anj
Form:	rg1
Visit code:	b
Date of visit:	12jan07
Enrollment must be done on or before 3 May 2007	
Transaction type:	add
Transaction time:	1/16/2007 11:38:48 AM
Keying rates:	2,491 keystrokes per hour
Verify checks:	0 per 100 items
DE oper:	lam
Click to print Screening labels	<input type="button" value="Print >"/> <input type="button" value="Continue >"/>
Messages	
ADD 2ND KEYING : 1003 anj b rg1 12jan07 lam	

Please note that you cannot change the participant's ID number, patient code, or registration date after the RG form is entered, nor can you delete an RG form, so verify that the information is correctly entered before saving the form. If an error is made when completing or keying any of these items, please contact the DCC.

4.3. Screening visit labels

Once you have keyed the Registration form without errors and saved the data by clicking on the *OK* button, a screen will appear confirming that you have successfully registered the participant (see figure 4.2b). Be sure to first set your internet browser's POP-UP blocker to OFF. From this confirmation screen, print the labels for the participant's screening visit by clicking on the *Print* button next to "*Click here to print Screening labels.*" A screen with the participant's labels appears in a PDF file format which can then be printed using the Adobe PDF Printer icon or the PDF File/Print menu (see figure 4.3a). For detailed instructions on printing labels, see section 8.2.

4.3a Screening visit labels PDF file (figure)

GpCRC - Gastroparesis Consortium Network
UMI

- Insert one sheet of MACO ML-5000 labels in the printer's **single sheet feeder**
- Print the labels using the Adobe PDF print button or File/Print menu from the PDF window which is opened on the right
- UNCHECK** the following options when the PDF "Print" confirmation box appears:
 - Shrink oversized pages to paper size
 - Expand small pages to paper size
 - Auto-rotate and center pages
- Replacement** MACO ML-5000 InkJet Labels: Call 800-221-9983 (8.5" x 1" sheet, 1" x 1.5" labels, 50 labels/sheet)
- Close (X) the Adobe PDF window when printing finishes
- TIP: If Adobe PDF window is not visible, click the Adobe window on the taskbar.
- TIP: Browser pop-up window blockers must be turned off or bypassed

< Previous

Messages
1 of 1

ADD 2ND KEYING : 9521 xxx b rg1 15nov06 kpy

4.3. Screening visit labels

Screening visit labels can also be printed at a later time by using the Print Blank Labels task and keying, visit = **b or s** for screening visit and the study code (**1** for Registry, **2** for NORIG, **3** for GLUMIT, **4** for APRON). This is described in detail in section 8.2.

SOP III: GpCRC Web-Based Data Management System

5. Eligibility checking and participant enrollment

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5.5.	Authorized override of ineligibility.	57

5.1. Introduction

A goal of every GpCRC study or trial is to enroll into the GpCRC study (e.g., Registry, GLUMIT-DG) or randomize into a trial (e.g., NORIG, APRON) eligible patients with complete baseline data. Each study has its own Eligibility task which checks on completeness of baseline data collection, on time window requirements for data values, and on consistency with the study's eligibility criteria. For GpR, enrollment will not be allowed if '?' or 'm' is entered on any forms. In NORIG and GLUMIT-DG, the use of '?' will be allowed only for certain form items.

Note that the permissible time window checks for various screening tests and/or results are determined in the Eligibility task from the time of test or data collection either to the registration date or by counting backwards from the current date, which is assumed to be the enrollment date, depending on the protocol requirements.

5.2. Eligibility checking

Eligibility checking must be completed successfully prior to enrollment into the GpCRC study (e.g, Registry, GLUMIT-DG) or randomization into a trial (e.g., NORIG, APRON). The Eligibility task is the first step in the Enrollment task on the MAIN TASKS menu. Enrollment can only occur if all eligibility checks have been passed.

To check eligibility for a participant,

1. Select *Enroll* from the MAIN TASKS menu
2. Key that participant's ID number, patient code and study number (see figure 5.2a)
3. Click on *Submit* to continue.

5.2a Eligibility prompt screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Enter patient information to check eligibility.

Patient ID
Patient code
Study 1=Registry 2=trialxxx 3=trialzzz



Messages

Check eligibility: 199
Enter patient ID

5.2. Eligibility checking

If a patient is **not eligible**, then a screen will appear with all Eligibility STOPS for that participant listed as in figure 5.2b.

5.2b Eligibility STOPS (figure)

If eligible, the patient will be enrolled

Patient ID

Patient code

Study 1=Registry

< Previous Submit >



5011 (kkm) not eligible for REGISTRY

Age=51 gender= m

STOPS:

BP has ?
 EN has ?
 LR has ?
 UG has ?
 CG112 = 2 consent not given; disagrees with BC form

Messages

If the reason(s) for ineligibility can be resolved, such as a screening test that was outside the allowed time window can be rescheduled, then proceed to resolve the listed problems.

If the reason(s) for ineligibility cannot be resolved, such as the participant was found to have a stomach obstruction after their upper endoscopy procedure, then inform the patient of their status. Complete and key the Registry Enrollment (EN) form. This will provide the list of reasons why this participant was ineligible and will no longer be in active screening.

The Eligibility task must be re-run until there are no eligibility STOPS remaining and an enrollment confirmation screen appears. If it is not clear why there are STOPS, please contact the DCC for help in resolving the problem.

5.3. Patient enrollment in GpR or GLUMIT-DG

A participant may be enrolled into the Gastroparesis Registry or the GLUMIT-DG study once all eligibility STOPs have been resolved and an enrollment confirmation screen appears in the window. To enroll a participant,

1. On the day of enrollment, confirm that the participant still consents to study enrollment
2. Complete and key the Enrollment (EN) form (use visit code = **e** for GpR or **en** for GLUMIT)
3. Select *Enroll* from the MAIN TASKS menu
4. Key the ID number, patient code and study number of the participant
5. Click *Submit*
6. The enrollment confirmation screen will be in view (see figure 5.3a). Click *Continue* at the bottom of the screen to print the visit time window listing.

5.3a Enrollment confirmation screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium					WFU
Confirmation Number: registry-wfu3enroll-md					
Study:	REGISTRY				
GpCRC ID:	5011				
Patient code:	kkm				
Enrollment date:	15JAN07				
Transaction type:	Enrollment				
Transaction time:	1/15/2007 1:17:32 PM				
DE oper:	md				
Enrollment #:	3				
GpCRC Registry Visit Windows					
ID	Visit	Target date	Date window opens	Date window closes	
5011	f016	5/7/2007	3/12/2007	7/2/2007	
5011	f032	8/27/2007	7/3/2007	10/22/2007	
5011	f048	12/17/2007	10/23/2007	2/11/2008	
5011	f064	4/7/2008	2/12/2008	6/2/2008	
5011	f080	7/28/2008	6/3/2008	9/22/2008	
5011	f096	11/17/2008	9/23/2008	1/12/2009	
Messages					
REGISTRY - Check eligibility: 5011 kkm md					
Enrollment complete					

5.3. Patient enrollment in GpR or GLUMIT-DG

If the patient is not enrolled at this time due to unresolved eligibility STOPS, keep in mind that a screening window for a test or procedure may close. The permissible time window checks are determined in the Eligibility task from the time of test or data collection either to the registration date or by counting backwards from the date the task is run. Therefore, by waiting to enroll the participant on a future date, the time window may close.

For a participant that requires specific dates for their follow-up visit schedules, the Projected Visits report can be run to help determine the best enrollment date. This report is displayed after selecting the *Listings* task on the MAIN TASKS menu and then clicking on the *Projected visits* option (see section 9.16.).

The visit time windows listing may also be printed at a later time from the *Listings* task on the MAIN TASKS menu by selecting the *Visit windows* option (see section 9.13).

Labels for use at follow-up visits may be printed at any time from the *Print* task on the MAIN TASKS menu by selecting the *Labels* option (see section 8.2).

The set of forms for each follow-up visit should be printed from the GpCRC website: <http://www.jhucct.com/gpcrc/closed/forms/dataforms.htm> (i.e., section 8.1). The DCC suggests not printing these forms way in advance of the follow-up visit date, due to possible form revisions that may occur in the interim.

An e-mail will be sent to the DCC and other GpCRC investigators when a participant has been enrolled.

5.4. Patient randomization in NORIG or APRON

The enrollment program is used to randomize an eligible patient in the NORIG or APRON trial. Randomization does not happen unless all checks have been passed and the enrollment task has been run. Note that the time window checks for randomization are determined by counting backward from the current date.

On the day the participant is to be randomized into NORIG or APRON, confirm their consent and complete the Randomization (RZ) form.

To randomize a patient, click on *Enroll* from the MAIN TASKS menu. Enter the ID number, patient code, and study code of the patient you wish to randomize (**2** for NORIG, **4** for APRON). Press *Submit* to continue.

If the patient is not eligible, the eligibility stops will be listed. If possible, resolve each issue and then re-run the enrollment task. If an issue cannot be resolved, then the patient may not participate in the trial.

If the patient is eligible, the data system asks if you wish to randomize the patient now. To randomize the patient, enter “**1**” (1=yes) in the box next to the question, “Randomize now?” For APRON, a randomization confirmation screen will appear that includes the assigned study drug bottle ID number that is to be given to the patient. The confirmation screen also includes the visit windows schedule for the patient. You will be asked if you want to print the visit windows listing from this screen (click continue to print).

For NORIG, the Drug Dosing Determination and Dispensing (DD) form must be entered **after** Randomization. Once the DD form is entered, the assigned study drug, with bottle ID number be displayed (see figure 5.4a).

An e-mail will be sent to the DCC when a patient has been randomized.

5.4. Patient randomization (NORIG)

5.4a Drug dispensing confirmation screen (figure)

Data System GpCRC - Gastroparesis Clinical Research Consortium WFU

Confirmation

Confirmation Number: norig-WFU2dd1add-iam

Study: NORIG
GpCRC ID: 5090
Patient code: fwn
Form: dd1
Visit code: f03
Date of visit: 16mar10
Study drug: 25-4381

Transaction type: add
Transaction time: 3/16/2010 2:18:16 PM
Keying rates: 1,671 keystrokes per hour
Verify checks: 0 per 100 items
DE oper: iam

[Continue >](#)

Messages

ADD 2ND KEYING : 5090 fwn f03 dd1 16mar10 iam
Transaction complete

Internet | Protected Mode: On 100%

Office CCT - GoTo... GpCRC Confiratio... Untitled - Paint 2:24 PM

5.5. Authorized override of ineligibility

This feature is enabled only at the DCC.

If you know the participant will not pass all of the eligibility checks, there is an option to override the checks. Contact the DCC in writing, with an explanation of the problem and a justification for the override. The DCC will review the request and if approved, will complete the override at the DCC when you are ready to enroll the participant. You will need to be in contact with the DCC **prior** to when you want to enroll the participant, and additional information (e.g., copies of forms and reports) may need to be provided.

SOP III: GpCRC Web-Based Data Management System

6. Study drugs

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6.1. Dispense study drug

For NORIG:

After a patient is randomized in NORIG, you will need to enter the Drug Dosing Determination and Dispensing (DD) form to receive the patient and visit specific study drug bottle ID numbers. The data system will print a confirmation of NORIG study drug dispensing, which includes the bottle number IDs of the study medication to be given to the patient.

For APRON:

The randomization confirmation screen will include the assigned study drug bottle ID number.

For Both trials:

Once the study drug bottles are dispensed to the participant, the Study Drug Dispensing and Return (RD) form must be completed and keyed into the data management system.

6.2. Study drug menu screen

The study drug inventory task will display a listing of either the study drugs dispensed or available for the study.

1. Click on *Study Drugs* on the MAIN TASK menu
2. Click on *Drug Inventory* on the STUDY DRUG menu
3. Key the type of inventory display (**1**=study drugs dispensed, sorted by bottle number; **2**=study drugs dispensed, sorted by patient ID; **3**=available study drugs) and the study number (e.g., **2**=NORIG, **4**=APRON) in the study drug inventory request screen (see figure 6.4a)
4. Click on *Submit*

6.2a Study Drug Menu (figure)

GpCRC - Gastroparesis Clinical Research Consortiu

What do you want to do?

Drug Inventory >

Dispense Drug >

< Previous Exit

Messages

Select an action

6.3. Study drug inventory

The study drug inventory task will display a listing of either the study drugs dispensed or available for the study.

1. Click on *Study Drugs* on the MAIN TASK menu
2. Click on *Drug Inventory* on the STUDY DRUG menu
3. Key the type of inventory display (**1**=study drugs dispensed, sorted by bottle number; **2**=study drugs dispensed, sorted by patient ID; **3**=available study drugs) and the study number (e.g, **2**=NORIG, **4**=APRON) in the study drug inventory request screen (see figure 6.4a)
4. Click on *Submit*

6.4a Study drug inventory request screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Study drug inventory

Type of inventory 1 = study drugs dispensed, sorted by bottle number
2 = study drugs dispensed, sorted by patient ID
3 = available study drugs

Study 2 = trialxxx 3 = trialzzz

Messages

dcc
Enter type of display

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7. Data entry of forms

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7.1. Instructions for data entry

The data forms completed for GpCRC participants constitute the official database for the specified study. All of the GpCRC study findings and results will be derived from analyses of the electronic database. Responsibility for data entry resides at each clinical site.

It is extremely important that the computerized data files match the information recorded on the paper forms. All edits to the paper forms must be dated, initialed, and a brief explanation given as to why an item was changed by the appropriate staff member. If a change is made to a paper form, the change must be made to the electronic record also. These changes, first to the paper form and then to electronic record, should be made as simultaneously as possible.

Data entry operators are key to fulfilling these quality assurance requirements. If the electronic database is incorrect, the conclusions drawn from analyses of the database are likely to be incorrect.

The GpCRC data system has several features designed to promote accuracy of data entry:

- Range checks at the time of data entry
- Consistency checks at the time of data entry
- Double keying of all data items (except General Comments), with checks on agreement between keyings

These features may slow the data entry process because the data entry operator will have to resolve problems in order to complete the keying. Hence, it is to everyone's advantage to complete the paper forms carefully, correctly, and accurately so that they are as free of problems as possible.

NOTE that data can be saved only for a form keyed twice with no data entry errors. You cannot save your work in the middle of keying a form.

To add, browse, change, or delete a form, click on the *Data entry* task on the MAIN TASKS menu screen (see figure 2.4a). The DATA ENTRY menu screen will appear as in figure 7.1a. To select a data entry option, click on the option's button and the data entry task entry screen will be in view. Clicking on the *Previous* button returns the user to the MAIN TASKS menu.

7.1. Instructions for data entry

7.1a DATA ENTRY menu screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Enter, browse, change, or
delete data forms for a patient

Add a data form >

Browse a data form >

Change a data form >

Delete a data form >

< Previous

Messages

Data entry
Select an action

To initially key a form's data, click *Add a data form* on the DATA ENTRY menu, and then enter the key variables from Section A of the form (see figure 3.4b). These are the variables that uniquely identify the form data.

- Patient ID - four digit number that uniquely identifies the GpCRC study participant (item 2 on every form)
- Patient code - three character code that uniquely identifies the GpCRC study participant (item 3 on every form)
- Date of form - date form was completed, i.e., the visit date or the date that the hard copy form was completed, not the data entry date (item 4 on every form)
- Visit code - eg, **b**, **f016**, **f032**, **f064**, ... (item 5 on every form)
- Form + revision code - the form code and revision number, e.g., **rg1**, **1r1**, **st2**... (item 6 on every form)
- Study number - key the specified study number (e.g., **1** for Gastroparesis Registry; **2** for NORIG; **3** for GLUMIT-DG; **4** for APRON) (item 7 on every form)

7.1. Instructions for data entry

Each data item must be keyed twice. After entering this information, hit **ENTER** or click on *Submit* to access the data entry screen for the form. Note that after the key variables for the RG form are submitted, that a prompt appears requesting confirmation of the study. Type the study name (eg, ‘**registry**’ for the Registry, or ‘**glumit**’ for the GLUMIT-DG study, ‘**norig**’ for the NORIG trial or ‘**apron**’ for the APRON trial), then click on *OK*.

Data should be keyed exactly as they appear on the form. After keying a field, press **ENTER** or click in the next box to advance to the next data field. When there are gaps between fields, use the scroll bar and click on the field to be keyed rather than pressing the **ENTER** key repeatedly. To go to a previous field, either use the mouse to click in that box or press **shift-Tab** to go back through the fields.

The final screen for each form has a General Comments area where excess comments, marginal notes or other comments may be keyed.

Data entry keying of various types of fields (see Appendix 11.3 for a summary table):

Generally, you will completely fill the data entry space provided for each response; the exceptions to this are, "Other (*specify*)" responses (which may not require the 35 characters allowed), the General Comments fields (which may or may not include responses) and special response codes: r (refused), d (don't know), m (missing), n (not applicable), ? (query: temporarily missing). Appendices 11.4 and 11.5 provides additional information for special response codes.

Signatures are not keyed — type **1** if the signature is present.

Numeric fields must be filled completely; the staff members recording data items on forms should use leading and trailing zeros as needed. For example, hemoglobin (item 17 on Form LR1) has the format • . Suppose the lab report gives a value of 1.0. The person recording the data on the form should write in 0 1 • 0. The data system operator keys **010**. **Note that punctuation marks for numeric data (decimal points and commas) are not keyed.**

For “**all that apply**” items (such as item 9 on Form BH1), key a **1** if the item is checked; if the item is not checked, leave the field for that item blank. There must be at least one response item keyed. The program will not allow required items to be bypassed by leaving blank.

The **General Comments fields** are used to record the excess response in an "Other (*specify*)" item that exceeds the 35 characters allowed, and any marginal notes or other comments. The General Comments area includes 5 lines each accepting 75 characters and is the last screen to appear when keying a form. This is not a required data item for system edit checks; however, there are situations in which information must be keyed or a DCC audit check will be initiated. You can key the General Comments only area during the second keying of the form, then press **ENTER** to save.

7.1. Instructions for data entry

Note that **use of a question mark symbol, '?'**, in a comment or specify item field will result in an edit message; instead of keying a question mark, indicate the uncertainty in the response by keying 'possibly', 'quest', 'maybe', etc. in the comment or specify field.

After an item is keyed and the **ENTER** key pressed, the system will perform a series of checks to see that responses are in the correct format, within the allowable range, and consistent with other responses provided on the form. When these checks find an error, the error must be corrected before the data entry operator can continue keying other items. A message at the bottom of the screen will help to identify the error. Figure 7.1b shows the error message received when the date for item 8 on the EG form was keyed using an invalid format.

7.1b Example of a system data entry error message (figure)

GpCRC - Gastroparesis Consortium Network UMI

REGISTRY: EG - Upper Endoscopy Documentation (eg1)

1 Clinic ID	umi
2 Patient ID	9521
3 Patient code	xxx
4 Visit date	17nov06
5 Visit code	b
6 Form and revision	eg1
7 Study	1
8 Date of upper endoscopy	310ct06
9a Gastroparesis symptoms	<input type="checkbox"/>
9b Anemia	<input type="checkbox"/>
9c Abdominal pain	<input type="checkbox"/>
9d Gastrostomy tube	<input type="checkbox"/>
9e Other reason for procedure	<input type="checkbox"/>
9e Specify other reason for procedure	<input type="text"/>
10 Normal esophagus	<input type="checkbox"/>
10a Esophagitis	<input type="checkbox"/>
10b Barrett's esophagus	<input type="checkbox"/>
10c Hiatal hernia	<input type="checkbox"/>
10d Other esophageal finding	<input type="checkbox"/>
10d Specify other finding	<input type="text"/>
11 Normal stomach	<input type="checkbox"/>

Messages

ADD 1ST KEYING : 9521 xxx b eg1 17nov06 kpy

8 Date of upper endoscopy ==> date format: ddmmmyy

Error messages:

The error must be corrected before the data entry technician can continue keying other items, continue to the second data entry or save the data to the database.

An ERROR message can be resolved in one of three ways: by correcting the keyed value, by keying a ? (query code) to indicate that the item is under review, or by keying a correction to an associated item that will render the data consistent. When an ERROR message appears, the data entry operator should check the form to be sure that the data were keyed as written on the form. If

7.1. Instructions for data entry

the data were keyed as written, but an error is noted on the form (e.g., an item was answered that should have been skipped), the data entry operator may enter ? for the item(s) in question, and the ERROR message should disappear. These should be flagged on the hard copy to the appropriate staff member's attention. The items marked ? will appear in edit queries from the DCC for resolution until the ? is replaced with a response or other data entry code. Appendices 11.4 and 11.5 give more information on missing value codes and their appropriate use.

Alternatively, if the person who completed the form is available, the item(s) in question may be edited on the paper form (every edit must be initialed and dated by the appropriate staff member) and the corrected data then entered. **Edits must be verified — the data entry person should not simply change the data on the form to what s/he thinks the response should be.** This is a serious action that could cast doubt on all of that clinic's results. The reason given for why the form item is being changed should be keyed in the General Comments field.

If the data were keyed correctly and the form was completed correctly and there was still an error, write down the error message, print the screen, key ? for items that you cannot key as completed, and contact the DCC for further assistance.

Appendix 11.6 is a summary table of the most common types of data error message and their resolution.

Double data entry:

The data for each form must be keyed twice. After entering the last item of the first keying, a pop-up window appears with instructions to press ENTER twice to check the first keying for inconsistencies and other data errors (see figure 7.1c).

7.1. Instructions for data entry

7.1c Form check after first data entry keying (figure)

GpCRC - Gastroparesis Consortium Network TU

14d Native Hawaiian/Pacific Islander

14e White 1

14f Refused

15 Highest educational level

16 Currently employed 1

17 Current occupation

18 Hours/week work each week

19 Missed 2 weeks of work for Gp

20 Occupational history category

20 Specify other category

21 Marital status

22 Annual household income

23 Source of patient

23 Specify other source

24a Patient ID

24b Patient code

25 Coordinator PIN

26 Coordinator signed (y=1) 1

27 Date form reviewed

General Comments:

Messages

ADD 2ND KEYING : 9521 xxx b rp1 15nov06 kpy

15 Highest educational level ERROR: First keying - 4

Once all consistency checks from the first keying are resolved, a pop-up window appears with instructions to press ENTER once more as in figure 7.1d. The system then saves the responses from the first keying, clears the responses from the data entry screen, and sets the cursor to begin the second keying.

7.1d Clear screen to begin second data entry keying (figure)

GpCRC - Gastroparesis Consortium Network TU

8 Signed informed consent 1

9 Date of birth

10 Age at last birthday

11 Patient 18 or older 1

12 Gender 2

13 Ethnic category 2

14a American Indian/Alaska Native

14b Asian

14c Black/African American

14d Native Hawaiian/Pacific Islander

14e White 1

14f Refused

15 Highest educational level

16 Currently employed 1

17 Current occupation

18 Hours/week work each week

19 Missed 2 weeks of work for Gp

20 Occupational history category

20 Specify other category

21 Marital status

22 Annual household income

23 Source of patient

Messages

ADD 1ST KEYING : 9521 xxx b rp1 15nov06 kpy

8 Signed informed consent

Microsoft Internet Explorer

Press enter twice to check form

OK

7.1. Instructions for data entry

If the second keying of an item does not agree with the first keying, the value of the first keying will be displayed in the lower left corner of the screen, as in figure 7.1e below. If the first keying was correct, enter the correct value and press **ENTER**. If the second keying was correct, press **ENTER** to continue to the next field.

7.1e First and second keying do not agree (figure)

The screenshot shows a web browser window titled "GpCRC - Gastroparesis Consortium Network" with "TU" in the top right corner. The main content area contains a data entry form with the following fields and values:

14c	Native Hawaiian/Pacific Islander	
14e	White	1
14f	Refused	
15	Highest educational level	4
16	Currently employed	1
17	Current occupation	
18	Hours/week work	
19	Missed 2 weeks of	
20	Occupational history	
20	Specify other category	
21	Marital status	
22	Annual household income	
23	Source of patient	04
23	Specify other source	
24a	Patient ID	9521
24b	Patient code	xxx
25	Coordinator PIN	903
26	Coordinator signed (y=1)	1
27	Date form reviewed	15nov06
General Comments:		

A "Microsoft Internet Explorer" pop-up window is overlaid on the form. The window contains the text: "To save data, click OK -- DO NOT click OK more than once -- saving data may take a minute or more". Below the text are "OK" and "Cancel" buttons.

At the bottom of the browser window, a "Messages" pane displays the text: "ADD 2ND KEYING : 9521 xxx b rj 1 15nov06 kpy".

Since data keyed in the General Comments area are not checked for consistency and whatever is keyed during the second keying is retained in the electronic database, General Comments may be keyed once at the end of the second keying. Press **ENTER** to save.

Once all data entry errors have been corrected, click the *OK* button *ONCE* in the pop-up window shown in figure 7.1f to save the data entry values to the electronic database.

7.1. Instructions for data entry

7.1f Save data to the database (figure)

The screenshot shows a web browser window titled "GpCRC - Gastroparesis Consortium Network" with the URL "TU". The main content area displays a list of data entry fields, each with a corresponding input box. The fields are numbered 8 through 23. A Microsoft Internet Explorer error dialog box is overlaid on the form, displaying a yellow warning icon and the text "Press enter to start keying 2". The dialog box has an "OK" button. At the bottom of the browser window, a status bar shows "Messages" and "ADD 1ST KEYING : 9521 xxx b rg 1 15nov06 kpy".

Confirmation screen:

After a form has been keyed twice, all consistency checks are passed and the data saved by clicking on the *OK* button, a confirmation screen appears (see figure 4.2b). This confirms that the data for that form have been saved in the electronic database.

Click *Continue* and the screen returns to the MAIN TASKS menu.

After keying the form, the data entry person should check the “keyed” box on the first page of the form and initial and date the form hard-copy.

Summary reminders:

- (1) Guidelines for the keyboard during data entry:
 - **Num Lock on, Caps Lock off, Insert off**
 - Use numeric keypad to ENTER numeric data
 - Press **ENTER** after each item
 - Press **Shift-Tab** or use the mouse to go back to previous items
 - Use the mouse to navigate around the screen
- (2) Data can be saved only for a complete form and only after double data entry. You cannot save your work in the middle of a form.
- (3) The data entry person should initial and date the form after the confirmation screen appears.

7.2. Browsing data

After a form is keyed and saved, it is possible to look at what was entered. The safest way to do this is to browse or look at the form without being able to make changes to it.

1. From the DATA ENTRY screen (see figure 7.1a), click on *Browse a data form*.
2. Key the information that identifies the form to be browsed: Patient ID, visit code, form + revision code, and study number in the browse data form prompt screen.
3. Key an asterisk (*) to request all items for that identifier.
4. Click the *Submit* button and the browse data form screen (see figure 7.2a) is displayed.
5. Click on the *Browse* button to the left of the forms listed to see the contents of the form.
6. A screen with all of the data for that form as it appears in the database will be displayed, but the form data may not be changed.

7.2a Browse data form (figure)

GpCRC - Gastroparesis Consortium Network UMI

To list forms in the database available for browsing, enter items (or * for all), select SORT options and click "Submit"

To browse a form, click the "Browse" button

Sort by

Patient ID

Visit

Form + revision

Study 1-Registry

< Previous Submit >

Study: REGISTRY

	ID	Patient code	Visit	Form	Date of form	Query
Browse	9521	xxx	b	lr0	17NOV06	
Browse	9521	xxx	b	pe0	15NOV06	
Browse	9521	xxx	b	rg1	15NOV06	
Browse	9521	xxx	b	se0	17NOV06	

Number found: 4

Messages

BROWSE DATA FORM

7.3. Changing data

To correct an error or update information on a form that has been keyed and saved, the Change task is used.

1. From the DATA ENTRY screen (see figure 7.1a), click on *Change a data form*.
2. Key the information that identifies the form to be edited: Patient ID, visit code, form + revision code, and study number in the change data form prompt screen.
3. Key an asterisk (*) to request all items for that identifier, e.g., to retrieve all forms for a specified participant, in a given study, key the Patient ID, the study number, and then key asterisks for visit code and form + revision code. Keying all asterisks and a study number retrieves all forms in the data system for the specified study.
4. Click the *Submit* button and the change data form screen (see figure 7.3a) is displayed.

7.3a Edit data form (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To list forms in the database available for change, enter items (or * for all), select SORT options and click "Submit"

To change a form, click the "Edit" button

	Patient ID <input type="text" value="1111"/>	Sort by	<input checked="" type="radio"/>
	Visit <input type="text" value="*"/>		<input type="radio"/>
	Form + revision <input type="text" value="*"/>		<input type="radio"/>
	Study <input type="text" value="1"/>		1=Registry

Study: Registry

	ID	Patient code	Visit	Form	Date of form	Query
<input style="border: 1px solid black;" type="button" value="Edit"/>	1111	yrx	b	bp1	15SEP06	?
<input style="border: 1px solid black;" type="button" value="Edit"/>	1111	yrx	b	qf1	15SEP06	?
<input style="border: 1px solid black;" type="button" value="Edit"/>	1111	yrx	b	bc1	15SEP06	

Messages

EDIT DATA FORM

Enter patient ID or *

5. Each form on the resulting list will have an *Edit* button to the left of the form list. Click on this button to display the contents of a form.

7.3. Changing data

- A script prompt window screen requests that the patient ID, visit, form, and study number items (separated by commas) be re-entered as verification that the form you clicked on is the form you want to change (see figure 7.2b).

7.3b Edit data form - verification of record ID (figure)

The screenshot shows a web browser window titled "GpCRC - Gastroparesis Consortium Network" with a "UMI" user. An "Explorer User Prompt" dialog box is open, displaying a script prompt: "PLEASE CONFIRM: GpCRC ID, visit, form, study (separated by commas)". The input field contains "9521,b,pe0,1". The dialog has "OK" and "Cancel" buttons.

The main browser window shows instructions for listing and editing forms. It includes input fields for "Patient ID" (9521), "Visit" (b), "Form + revision" (pe0), and "Study" (1). There are "Sort by" radio buttons for Patient ID, Visit, and Form + revision, and a "1=Registry" option. "Previous" and "Submit" buttons are visible.

Below the input fields, a table displays the form data for the "Registry" study:

ID	Patient code	Visit	Form	Date of form	Query
9521	xxx	b	pe0	15NOV06	

The table has an "Edit" button next to the first row. Below the table, it says "Number found: 1" and has a "Previous" button. At the bottom, there is a "Messages" section with the text "EDIT DATA FORM".

- A screen with all of the data for that form as it appears in the database will be displayed.
- To change an item: delete the old data in the specified item's entry cell and type in the new information. Press ENTER when finished.
- All edits/consistency checks are performed by the data system; if no errors are flagged, then press ENTER twice (to save the data) and click on *OK*.
- A confirmation screen for the changed form record will appear.

If the change in the data system occurs as a result of changes to the original hard copy form, that change must be reflected on the original form (incorrect item crossed out, dated, initialed, and reason written in margin) and the paper form must be **re-signed** and dated by the coordinator or appropriate staff member or an additional hard copy form must be completed.

The data entry technician should initial the original or initial the additional hard copy form once the data change has been keyed, saved, and the confirmation screen has appeared.

7.4. Deleting data

If an entire form is found to be incorrect (e.g., data entered for the wrong participant or key variables were entered incorrectly), the form must be deleted.

1. Go to the DATA ENTRY screen (see figure 7.1a) from the MAIN TASKS menu.
2. Click on *Delete a data form*.
3. In the prompt screen (see figure 7.4a), enter the key identifiers for the form twice.
4. Click on *Submit*.

7.4a Delete a data form screen (figure)

GpCRC - Gastroparesis Consortium Network TU

Enter key information to locate the form in the database.

Patient ID	<input type="text"/>	Confirm	<input type="text"/>
Patient code	<input type="text"/>		<input type="text"/>
Date of form	<input type="text"/>		<input type="text"/>
Visit	<input type="text"/>		<input type="text"/>
Form + revision	<input type="text"/>		<input type="text"/>
Study	<input type="text"/>	1=Registry	<input type="text"/>

Messages

DELETE: kpy
Enter patient ID

Use this function with caution.

Remember that once a participant's ID number, patient code or registration date for a study has been assigned after the RG form is keyed and saved, these codes cannot be changed. A saved RG form cannot be deleted. If the visit date is incorrect on the saved RG form, please notify the DCC.

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8. Printing

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8.1. Blank forms or form sets

Blank forms should be printed from the GpCRC website <http://www.jhucct.com/gpcrc/closed/forms/dataforms.htm> to ensure the most up to date forms are used. You may print individual data collection forms or print form sets for a particular study visit. Ensure that your internet browser's POP-UP blocker must be set to off.

8.2. Labels

The Print Labels function will enable printing of the labels needed for data collection forms and blood collection tubes at each participant visit. Please note that the DCC will supply a set of pre-printed ID number and name code labels, as well as labels for plasma and serum cryovials. These labels cannot be printed from the data system.

The sheet of labels displayed by the data system will be in a PDF file format, which can then be printed using the Adobe PRINT icon or File/Print menu. There is one set of labels per participant per visit per study, which will include all the labels needed for the forms and blood collection tubes at a particular study's visit. These include:

Self-administered forms for Registry:

- BD Beck Depression Inventory
- FD (Rome III Diagnostic Questionnaire)
- FQ Food Questionnaire Documentation AND Block Brief Food Questionnaire booklet
- GD Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI - SYM)
- PI Brief Pain Inventory
- QF SF-36 Health Survey
- SE State - Trait Anxiety Inventory (Self-Evaluation Questionnaire)
- UG Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)

Self-administered forms for NORIG:

- BD Beck Depression Inventory
- GD Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI - SYM)
- GS Gastrointestinal Symptom Rating Scale (GSRS) questionnaire
- PI Brief Pain Inventory
- PQ Patient Health Questionnaire (PHQ-15)
- QF SF-36 Health Survey
- SE State - Trait Anxiety Inventory (Self-Evaluation Questionnaire)

Self-administered forms for GLUMIT-DG:

- GD Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI - SYM)
- UG Patient Assessment of Upper Gastrointestinal Disorders - Quality of Life (PAGI-QOL)

Self-administered forms for APRON:

- GC Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)
- GD Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI - SYM)
- GS Gastrointestinal Symptom Rating Scale (GSRS) questionnaire

- PI Brief Pain Inventory
- PQ Patient Health Questionnaire (PHQ-15)
- QF SF-36 Health Survey
- SE State - Trait Anxiety Inventory (Self-Evaluation Questionnaire)

Blood collection administrative forms (same for Registry and NORIG):

- BP Blood Processing for Plasma and Serum (ship to local laboratory)
- BC Blood Collection for DNA (ship to Genetics Repository)

Blood collection tubes (same for Registry, NORIG, GLUMIT-DG and APRON)

- Blood for serum (red-gray top SST) (Registry)
- Blood for plasma (green top sodium heparin) (Registry, GLUMIT-DG, NORIG and APRON)
- Blood for the Genetics Repository (2 purple top NaEDTA) (Registry, NORIG and APRON)

Type of labels to use:

Use MACO Laser/Ink Jet White All-Purpose/Address Labels, MACO # MML-5000 1" x 1 ½" labels, 50 per page, 5000 per box, to be supplied by the clinic. Find a supplier by visiting <http://www.maco.com/where-to-buy.html>, or by doing an internet search for "MACO ML 5000 labels," or by checking with the clinic's office supplier. PPM 8 gives more details concerning the purchase and use of labels.

Screening visit labels:

The labels for screening visit b should be printed after registering a participant. Once you have keyed the Registration (RG) form and resolved all error messages and edits, a confirmation screen will appear confirming that you have successfully registered the participant. To print labels:

1. **Make sure your internet browser's POP-UP blocker is set to OFF**
2. Click on the *Print* button next to "*Click here to print Screening labels*" (see figure 4.2a)
3. A screen with the participant's labels appears in a PDF file format.
4. Insert one sheet of labels in the printer's single sheet feeder
5. Print the labels using the Adobe PDF PRINT icon or the PDF File/Print menu
6. **Uncheck** the following options when the PDF "Print" confirmation appears:
 - Shrink oversized pages to paper size
 - Expand small pages to paper size
 - OR Fit to printer margins
 - Auto-rotate and center pages

Follow-up visit labels:

Once a participant is found to be eligible and is enrolled in the study/trial, labels for the follow-up visits may be printed. To print these labels:

1. Go to the MAIN TASKS menu screen (see figure 2.4a)
2. Click *Print*
3. Click *Labels*
4. Key the Patient ID, Patient code, Study number, and the specific visit code. (see figure 8.2a)
5. Click on *Submit*
6. Print labels following the same directions given above for printing the screening visit labels.

8.2a Print Label screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To print labels, enter participant ID,
patient code, study, and visit code

Patient ID
Patient code
Study 1=Registry 2=trialxxx 3=trialzzz
Visit



Messages

Enter participant ID

If a patient's labels are lost or the screening visit labels were not printed from the RG form confirmation page, additional labels can be printed at any time for that participant and visit from the PRINT menu screen.

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9. Listings

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9.1. LISTINGS menu

The LISTINGS menu screen displays various activities available through the web-based data management system to produce automated listings or reports. These windows can then be printed if desired.

To access this menu, first click on *Listings* in the MAIN TASKS menu (see figure 2.4a). The screen shown in figure 9.1a will appear.

9.1a LISTINGS menu screen (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Select activity.

Active screenees >	Missing forms >
Enrolled/randomized >	Visits completed >
Current status >	Visits due >
Birthdays >	Visit windows >
Find Id or code >	Visit window closings >
?s >	Visit status >
Transactions >	Projected visits >
Transaction log >	Clinic demographics >
	Study demographics >

< Previous Exit

Messages

Select an action

Select an activity by clicking on the button for that activity. Each activity is described in detail in the remainder of section 9. Using the asterisk (*) code when allowed will select all patients, visits or forms, respectively. The study number codes are **1** for Registry, **2** for NORIG, **3** for GLUMIT-DG and **4** for APRON.

Clicking on the *Previous* button returns to the MAIN TASKS menu. Clicking on the *Exit* button will exit the system and return to the desktop.

Lists and reports can be printed using the PRINTER icon.

9.2. Active Screenees listing

The Active Screenees option will produce a list of the patient IDs, patient codes, registration dates, and last possible date for enrollment for all participants currently in active screening for a specified study (i.e., registered patients who have not been enrolled into a GpCRC study (e.g., Registry, GLUMIT-DG) or randomized into a trial (NORIG, APRON) or who have not been closed out of the study).

To display the Active Screenees listing, click on *Active screenees* on the LISTINGS menu. Key the study number, and the list will be displayed as in figure 9.2a.

9.2a Active Screenees listings (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To list **last date for enrolling or randomizing** patients, enter study

Study 1=Registry 2=trialxxx 3=trialzz



REGISTRY: Enrollment or randomization window still open

ID	Name code	Registration date	Last day for enrollment
1111	yrx	8/1/2006	11/29/2006

Registry: Total = 1

Messages

REGISTRY: END DATE FOR ENROLLMENT OR RANDOMIZATION
Enter study number

9.3. Enrolled/Randomized listing

The Enrolled/Randomized option will produce a list of the patient IDs, patient codes, registration dates, and the dates of enrollment/randomization for all participants enrolled/randomized in the specified study.

To display the Enrolled/Randomized listing as in figure 9.3a, click on *Enrolled/randomized* from the LISTINGS menu. Key the study number and click on *Submit*. Note that enrolled participants are listed for the Registry and GLUMIT-DG. Randomization only occurs for a treatment trial (NORIG and APRON).

9.3a Enrollment/Randomized listing (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To list **randomized or enrolled** patients, enter study

Study 1=Registry 2=trialxxx 3=trialzzz



REGISTRY: Enrolled patients

ID	Name code	Registration date	Date of enrollment	Age at registration
1111	yrx	01aug06	30oct06	

Registry: Total = 1

Messages

REGISTRY: DATE OF ENROLLMENT OR RANDOMIZATION
 Enter study number

9.4. Current Status listing

The Current Status option will produce a list of all participants registered in any GpCRC study at your center, the current study in which the participant is registered, the participant's current status (whether the participant is in screening, in follow-up, or is ineligible), whether or not the participant is registered in another GpCRC study and what the participant's status is in that other study. If the current status of a participant is ineligible (INEL) or closed out (CO) and is followed by an asterisk (*), the Registry Enrollment (EN) form or the Registry Closeout (CO) form has not been keyed; therefore, the participant is assumed to be ineligible because the screening window has closed or they are assumed to be closed out because they have registered for another study.

To display the Current Status listing as in figure 9.4a, select *Current status* from the LISTINGS menu.

9.4a Current status listing (figure)

GpCRC - Gastroparesis Clinical Research Consortium				
List current status for all patients				
	< Previous			
ID	Current Study	Current Status	Other Study	Status in other study
1001	Registry	FU		
1002	Registry	INEL		
1003	Registry	FU		
1004	Registry	FU		
1005	Registry	FU		
1006	Registry	FU		
1007	Registry	FU		
1008	Registry	FU		
1009	Registry	FU		
1010	Registry	FU		
1011	Registry	FU		
1012	Registry	FU		
1013	Registry	FU		
1014	Registry	FU		
1015	Registry	FU		

Messages

CURRENT STATUS

Current status in GpCRC

9.5. Birthdays listing

The Birthdays option will produce a list of birthdays occurring in the next 30 days and the participant's age at next birthday for all participants enrolled in any GpCRC study at your center.

To display the Birthdays listing as in figure 9.5a, select *Birthdays* from the LISTINGS menu..

9.5a Birthdays listing (figure)

GpCRC - Gastroparesis Consortium Network

Birthdays in the next 30 days

Study: REGISTRY

ID	Patient Code	Date of birth	Age on next birthday
8003	vvt	15jul1943	61
8032	jme	26jun1987	18
8036	cme	06jul1936	69

Study: trialxxx

ID	Patient Code	Date of birth	Age on next birthday
8004	fjx	21jun1952	53

[< Previous](#)

Messages

Listing of birthdays in next 30 days
[List birthdays in next 30 days](#)

9.6. Find Patient ID or Code (look up) function

The Find ID or Code function will display a participant's patient code for a given ID number, or the patient ID number for a given patient code.

To access the Find ID or Code function, go to the LISTINGS menu, click on *Find ID or code*, key either the Patient ID or Patient code and click on the *Lookup* button. The information is displayed in the window as in figure 9.6a below.

9.6a Find ID or Code function (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To lookup a patient code, given a patient ID, or vice versa, enter either the patient ID or patient code and click "Lookup"

Patient ID
Patient code

<u>Patient ID</u>	<u>Patient code</u>
1200	otc

Messages
ID - patient code lookup
Enter participant ID

9.7. Outstanding Queries (?s) report

The Outstanding Queries (?s) report displays a list of forms with unresolved queries. If a ? was entered for any item on a form, the form is considered incomplete. The DCC will periodically provide a listing of these forms to clinics for resolution. In the interim, clinics can produce a list on their own using the Outstanding Queries (?s) report. Appendix 11.5 provides detailed information on the use of the query code.

To display the report as in figure 9.7a, go to the LISTINGS menu, click on ?s. Key the patient ID, visit, and/or form + revision and study codes of the form(s) you wish to see on the Outstanding Queries (?s) list. To list all of the forms with ?'s for a specified study, enter an asterisk (*) for patient ID, visit, and form + revision items.

Each form on the resulting list will have an *Edit* button. Click on this button to bring up the form in CHANGE mode. Re-enter the patient ID, visit, form and study codes (separated by commas) in the script prompt window screen as verification that this form is the correct form to be changed. The data in the form can now be edited using the CHANGE function of the data system (see section 7.3).

9.7a Outstanding Queries (?s) report (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To list forms in the database with queries, enter items (or * for all), select SORT options and click "Submit"

To change a form, click the "Edit" button

<table border="0"> <tr><td>Patient ID</td><td>*</td><td><input type="text"/></td></tr> <tr><td>Visit</td><td>*</td><td><input type="text"/></td></tr> <tr><td>Form + revision</td><td>*</td><td><input type="text"/></td></tr> <tr><td>Study</td><td>1</td><td><input type="text"/></td></tr> </table>	Patient ID	*	<input type="text"/>	Visit	*	<input type="text"/>	Form + revision	*	<input type="text"/>	Study	1	<input type="text"/>	<p>Sort by</p> <p><input checked="" type="radio"/> Patient ID</p> <p><input type="radio"/> Visit</p> <p><input type="radio"/> Form + revision</p> <p>1=Registry 2=trialxxx 3=trialzzz</p>
Patient ID	*	<input type="text"/>											
Visit	*	<input type="text"/>											
Form + revision	*	<input type="text"/>											
Study	1	<input type="text"/>											



Study:
REGISTRY

<input style="border: 1px solid black;" type="button" value=" Edit "/>	ID	Patient code	Visit	Form	Date of form	Query
<input style="border: 1px solid black;" type="button" value=" Edit "/>	1111	yrx	b	bp1	15SEP06	?
<input style="border: 1px solid black;" type="button" value=" Edit "/>	1111	yrx	b	qf1	15SEP06	?
<input style="border: 1px solid black;" type="button" value=" Edit "/>	1111	yrx	b	bd1	15SEP06	?

Number found: 3

Messages

QUERIES LIST

9.8. Transactions report

The Transactions report provides a summary of data entry activity at your clinic for a specified study. To use the transactions report, select *Transactions* from the LISTINGS menu. To view a summary of forms entered, changed, and deleted in the current month, key the study number and enter a **1** to select the current month display option and click on *Submit*. This lists all of the transactions that have been entered during that month sorted by PIN of the data entry operator. A summary of transactions during the previous month (Display option **2**) and overall (Display option **3**) can also be displayed.

9.8a Transactions report (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Transactions by PIN

Select study: 1=Registry 2=trialxxx 3=trialzzz

Select display option: 1=Transactions this month
2=Transactions last month
3=All transactions

Number of REGISTRY transactions - Total (as of 11/7/2006)

PIN	Add	Change	Delete
199	5	25	0
Total	5	25	0

Messages
DE Activity
Enter study number

9.9. Transaction Log listing

The Transaction Log listing displays all web transactions done on a specified day (today or yesterday) or for the entire month for a specified study. A list with the patient ID, visit, form, form date, transaction, PIN, and date and time of transaction will be displayed as in figure 9.9a.

To display the Transaction Log listing, click on *Transaction log* on the LISTING menu. Key the study number and the number of the display option (1=Transactions today, 2=Transactions yesterday, 3=Transactions this month), and click on *List*.

9.9a Transaction Log listing (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Transactions Log

Select study: 1=Registry 2=trialxxx 3=trialzzz

Select display option: 1=Transactions today
2=Transactions yesterday
3=Transactions this month

Number of REGISTRY transactions June 2005 (as of 6/14/2007)

ID	Visit	Form	Form date	Transaction	PIN	DE date/time
8064	b	qf1	26may07	add	dcc	6/2/2007 10:29:32 AM
8064	b	pe1	26may07	add	dcc	6/2/2007 10:32:21 AM
8064	b	lr1	26may07	add	dcc	6/2/2007 10:33:48 AM
8064	b	bh1	26may07	add	dcc	6/2/2007 10:35:00 AM
8064	b	cg1	12may07	add	dcc	6/2/2007 10:36:21 AM
8064	b	bp1	26may07	add	dcc	6/2/2007 10:39:59 AM
8064	b	bd1	26may07	add	dcc	6/2/2007 10:41:10 AM
8064	b	bc1	12may07	add	dcc	6/2/2007 10:58:48 AM
8064	b	ad1	26may07	add	dcc	6/2/2007 10:59:42 AM
8064	b	qf1	13may07	change	dcc	6/2/2007 11:01:22 AM

Messages

Transactions Log

Enter study number

9.10. Missing Forms report

The Missing Forms report lists the patient ID, patient code, visit date (if any part of the visit was completed), and missing forms for participants with missing forms in the specified study. If the visit window has closed and no forms were keyed or drugs dispensed, the Missed Visit (MV) form will be listed as missing. Otherwise, specific forms for that visit that were not keyed will be listed.

To display the Missing Forms report, go to the LISTINGS menu and select *Missing forms*. Key the study number and click on *Submit*.

9.10a Missing Forms report (figure)

GpCRC - Gastroparesis Clinical Research Consortium

To list forms missing from the data system,
select the study and click "Submit"

Study 1=Registry 2=NORIG



Study: REGISTRY

ID	Patient code	Visit	Visit date	Missing form(s)
1064	icq	f032	13nov08	GD ID PE PI UG

Number of patients or visits = 1

Messages

MISSING FORMS LIST

Enter study number

9.11. Visits Completed report

The Visits Completed report provides a count of the number of visits completed, visits missed, and the number of forms data entered for each visit code and overall for the specified study. To view the Visits Completed report, select *Visits completed* from the LISTINGS menu. Key the study number. Click on *Submit* and the list of the visits completed and the number of forms keyed for a given GpCRC study is displayed as in Figure 9.11a below.

9.11a Visits Completed report (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Completed visits
Select study:
 1=Registry 2=NORIG

Study: REGISTRY

Visit	Number of visits		Number of forms
	Completed	Missed	
b	114	0	1903
e	110	0	110
f016	59	20	452
f032	29	22	262
f048	16	13	234
f064	3	4	52
f080	2	0	18
n	18	0	33
Total	351	59	3064

Messages

Visit Counts for TU
Enter study number

9.12. Visits Due listing

The Visits Due option will produce a list of participants with a visit target date in a given month for the specified study. To display the Visits Due listing, go to the LISTINGS menu screen and select *Visits due*. Key the study number, month (as a 2 digit number, e.g. **04** for April) and year (as a 4 digit number, e.g. **2007**) of interest and click on *Submit*.

A list of all participants with a target visit date in the month and year selected is generated as in figure 9.12a. The list also includes the visit window dates.

9.12a Visits Due listing (figure)

GpCRC - Gastroparesis Clinical Research

To list **visits due**, enter study, month (1-12) and year (4 digits) of visit target date

Study 1=Registry 2=NORIG

Month

Year



REGISTRY Visits due in 12-2008

ID	Patient code	Visit	Target date	Date window opens	Date window closes
1001	ths	f096	12/10/2008	10/16/2008	2/4/2009
1007	bsv	f080	12/2/2008	10/8/2008	1/27/2009
1025	zou	f064	12/8/2008	10/14/2008	2/2/2009
1026	moe	f064	12/3/2008	10/9/2008	1/28/2009
1029	ees	f064	12/29/2008	11/4/2008	2/23/2009

Messages

VISITS DUE

9.13. Visit Windows listing

The Visit Windows option will display a list of all visit window dates for a given participant in the specified study as in figure 9.13a below. The list includes the target, window open, and window close dates by visit code for all follow-up visits. To produce the Visit Windows listing by participant, go to the LISTINGS menu screen and select *Visit windows*. Key the patient ID and the study number and select *Submit*.

9.13a Visit Windows listing (figure)

GpCRC - Gastroparesis Clinical Research (

To display visit windows, enter the participant ID number and study number

 1=Registry 2=NORIG

Study: Registry
Date of enrollment: 07feb07

ID	Visit	Target date	Date window opens	Date window closes
1001	f016	5/30/2007	4/4/2007	7/25/2007
1001	f032	9/19/2007	7/26/2007	11/14/2007
1001	f048	1/9/2008	11/15/2007	3/5/2008
1001	f064	4/30/2008	3/6/2008	6/25/2008
1001	f080	8/20/2008	6/26/2008	10/15/2008
1001	f096	12/10/2008	10/16/2008	2/4/2009

Messages

VISIT WINDOWS

9.14. Visit Window Closings listing

The Visit Window Closings option displays a list of visits that will close in a user-defined time period for a specified study. To display the Visit Window Closings listing as in figure 9.14a, go to the LISTINGS menu. Click on *Visit window closings*. Key the study number and the number of days until the window closes. Click *Submit*.

9.14a Visit Window Closings listing (figure)

GpCRC - Gastroparesis Clinical Rese

List visit windows closing

Study 1=Registry 2=trialxxx 3=trialzzz
 Days Number of days until window closes



Registry Visit Window Closing in next 45 days

GpCRC ID	Patient Code	Visit Due	Date Visit Window Closes
1003	anj	f080	11/22/2008
1004	qii	f080	11/26/2008
1008	beo	f064	11/6/2008
1025	zou	f048	10/13/2008
1029	ees	f048	11/3/2008
1038	ymj	f048	11/13/2008
1039	ido	f048	11/13/2008
1059	oys	f032	10/27/2008

Messages

VISIT WINDOW CLOSING in next 45 days

9.15. Visit Status Report

The Visit Status Report option displays a list of the current study status for either a participant or a group of participants for a specified study. The codes used are:

- * = Visit completed
- M = Missed visit (MV form entered)
- O = Open Visit window
- X = Overdue visit (window is closed but no forms are keyed)
- I = Incomplete visit (MV form with some other visit forms are keyed)

To display the Visit Status Report listing in figure 9.15a, go to the LISTINGS menu. Click on *Visit Status*. Key the Study number. For a specified participant, key the Patient ID. For a group of participants, key an asterisk (*) in the Patient ID and a group code (1= all enrolled participants, 2=open visit window, 3=overdue visits, 4=any missed visits) then click on *Submit*.

9.15a Visit Status Report listing (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Visit status listing

Patient ID * for all patients

Select group

Study

1 = all enrolled patients
2 = open visit window
3 = overdue visits
4 = any missed visits
1=Registry 2=NORIG



Registry Visit Status as of 10/13/2008
Open visit windows

GpCRC ID	Patient Code	Date of Enrollment	f016	f032	f048	f064	f080	f096	f112	f128	f144	f160	f176	f192	Deceased
1003	anj	17Mar07	*	*	*	*	O								
1004	qii	21mar07	*	M	M	M	O								
1006	ews	08May07	M	M	M	M	O								

Messages

VISIT STATUS for Registry

9.16. Projected Visits report

The Projected Visits report lists the projected visit window schedule for a given enrollment/randomization date for a specified study. This can be helpful if a participant needs to know what his visit schedule would be if s/he were enrolled in the study on a given date.

To display the Projected Visits report as in figure 9.16a, go to the LISTINGS menu, select *Projected visits*, key the projected date of enrollment in a GpCRC study or randomization into a GpCRC treatment trial and the study number and click on *Submit*.

9.16a Projected Visits report (figure)

GpCRC - Gastroparesis Clinical Research Consortium

Projected Visit Dates

To display projected visit dates, enter the projected date of randomization (ddmomy) and the study

Projected date of randomization

Study 1=Registry 2=trialxxx 3=trialzz

**Registry Visit Windows
for projected enrollment = 15nov06**

Visit	Target date	Date window opens	Date window closes
f024	5/2/2007	2/7/2007	7/25/2007
f048	10/17/2007	7/26/2007	4/2/2008
f096	9/17/2008	4/3/2008	3/4/2009
f144	8/19/2009	3/5/2009	2/3/2010

Messages

Projected visit dates
Enter projected date of randomization

9.17. Clinic Demographics Report

The Clinic Demographics Report displays the demographic (sex/gender and ethnic or racial category) tables by study for all participants enrolled or randomized into a study in your clinic as in figure 9.17a below.

To generate your clinic's demographic report, go to the LISTINGS menu and click on *Clinic demographics*.

9.17a Clinic demographics report (figure)

GpCRC - Gastroparesis Clinical Research I

Demographics Enrollment Report for TU

Registry: Part A. Total

Inclusion Enrollment Report for TU
Study: Registry
13 October 2008

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown	
Hispanic	4	0	0	4
Not hispanic	77	14	0	91
Unknown	0	0	0	0
Total	81	14	0	95

Racial Category	Females	Males	Unknown	Total
Asian	0	0	0	0
Native Hawaiian	0	0	0	0
African American	7	0	0	7
White	71	14	0	85
Combination	0	0	0	0
Unknown	3	0	0	3
Total	81	14	0	95

Registry: Part B. HISPANIC REPORT

Racial Category	Females	Males	Unknown	Total

Messages

DEMOGRAPHIC REPORT
Demographic Enrollment Report

9.18. Demographics report

The Demographics report displays study-specific demographic tables for the enrolled or randomized participants by ethnicity and gender for all of the clinics combined as in figure 9.18a below. To generate the combined clinics' demographics report, go to the LISTINGS menu and select *Study demographics*.

9.18a Demographics report (figure)

GpCRC - Gastroparesis Clinical Research

Demographics Enrollment Report for GpCRC

REGISTRY: Part A. Total for ALL CLINICS

Inclusion Enrollment Report for ALL CLINICS
Study: REGISTRY
13 October 2008

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown	
Hispanic	8	0	0	8
Not hispanic	196	39	0	235
Unknown	0	0	0	0
Total	204	39	0	243

Racial Category	Sex/Gender			Total
	Females	Males	Unknown	
American Indian	2	0	0	2
Asian	0	0	0	0
Native Hawaiian	0	0	0	0
African American	15	4	0	19
White	182	35	0	217
Combination	2	0	0	2
Unknown	3	0	0	3
Total	204	39	0	243

REGISTRY: Part B. HISPANIC REPORT for ALL CLINICS

Racial Category	Sex/Gender			Total
	Females	Males	Unknown	

Messages

GpCRC DEMOGRAPHIC REPORT
GpCRC Demographic Enrollment Report

SOP III: GpCRC Web-Based Data Management System

10. Audit procedures

Purpose

- To check the completeness and accuracy of data entered into the electronic database

When

- Periodically (approximately monthly) as requested by the DCC

Procedures

1. The DCC will e-mail the clinics a list of forms to be audited.
 2. Within 14 business days of receiving the list from the DCC, the clinic will mail (via Fed Ex or trackable delivery) copies of these forms to the DCC for review. Clinics are **not** to fax forms. Any participant identifying information, e.g., patient's name on copies of lab results, must be blacked out.
 3. The DCC will review these forms by comparing the data on the paper form with the data entered in the electronic database.
 4. The DCC will return audit results in a Clinic Audit Report memo via e-mail. This report will summarize the discrepancies.
 5. If necessary, the clinic will use the CHANGE function of the data entry system to edit (correct or complete) the data in the database in response to the Clinic Audit Report.
 6. The clinic will return the Clinic Audit Report memo describing their actions to the DCC by fax. The response to each audit should be hand-written on the audit memo.
 7. Discrepancy rates will be calculated and clinics' discrepancy rates will be compared in performance report tables produced monthly by the DCC and for DSMB and Steering Committee meetings.
-

SOP III: GpCRC Web-Based Data Management System

11. Appendices

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Appendix 11.1. Clinic ID codes, Patient IDs, and site ID numbers

Clinic	Clinic ID	Patient IDs	Site ID number
Stanford University	SU	4001-4999	613
– California Pacific Medical Center	CPMC	4001-4999	613
Temple University	TU	1 001-1999	610
Texas Tech University	TTU	6 001-6999	637
University of Michigan	UMI	2 001-2999	611
University of Mississippi Medical Center	UMS	3 001-3999	612
Wake Forest University Health Sciences	WFU	5 001-5999	614

*Site ID numbers to be used in specimen banking at the NIDDK Biosample Repository (Fisher) and Genetics Repository (Rutgers Univ.) Site ID numbers assigned by RTI International for the NIDDK Data Repository.

Appendix 11.2. Forms for use with the tutorial

To complete the tutorial, 6 completed forms for the Registry study for visit b for a dummy participant (patient ID = 9521, patient code = xxx) must be entered. Print these forms from the GpCRC website: <http://www.jhucct.com/gpcrc/closed/studies/registry/SOPs/tutorialforms.pdf>.

These forms are for use with the tutorial **only**. The Clinic ID is left blank on the forms; your center's Clinic ID code will automatically be generated by the data system according to the log-on Clinic ID. The forms you will enter are:

- RG1 - Registration
- SE0 - Stait -Trait Anxiety Inventory (Self - Evaluation Questionnaire)
- LR0 - Laboratory Results
- PE0 - Physical Examination
- EG1 - Upper Endoscopy Documentation
- EN0 - Registry Enrollment

Note that these form versions are not the same as the data entry forms used to key actual study participants.

Appendix 11.3. Rules for data entry

Type of item	Rule	Other notes
All items	<ul style="list-style-type: none"> • Completely fill the data entry space • Key EXACTLY what is written • After keying, press ENTER (initiates system data checks) or click in next item to be entered 	<ul style="list-style-type: none"> • EXCEPTIONS to filling all of the space are: Letter codes: alpha Center ID, visit code Special response codes Other (<i>specify</i>) field General comments fields • System edit error message appears if a required data item is left blank
Signatures	If present, key 1	If not present, key ?
Letter	<ul style="list-style-type: none"> • Left-adjust • Trailing spaces left blank 	<ul style="list-style-type: none"> • Examples are password, Name Code, Center ID, Visit Code • Stored as lowercase in database
Numeric	<ul style="list-style-type: none"> • Key leading and trailing zeros • Do NOT key decimals or commas 	<p>Example of a numeric item format <u> </u>•<u> </u>:</p> <p>Actual response value = 1.0 Form recorded value = <u>0</u><u>1</u>•<u>0</u> Keyed value = 010</p>
Date	<ul style="list-style-type: none"> • Completely fill the data entry space • Key EXACTLY what is written 	<ul style="list-style-type: none"> • All dates formatted as ddmmmyy where yy=2-digit year. Birthdates require a 4-digit year.
Check all that apply	<ul style="list-style-type: none"> • If item checked, key 1 • If not checked, leave blank 	CAUTION: Make sure either ENTER is pressed after each possible response OR click in each field checked
Other, (<i>specify</i>)	<ul style="list-style-type: none"> • Key exactly as written • Up to 35 characters are allowed • Not case-sensitive 	<ul style="list-style-type: none"> • If response > 35 characters, key excess response in General Comments field • Do NOT use a question mark (?) or an ampersand (&) or plus sign (+) or equal sign (=) or asterisk (*) or quotes (“ or ’) in a response • All characters are automatically converted to lower case

Appendix 11.3. Rules for data entry

Type of item	Rule	Other notes
General Comments	<ul style="list-style-type: none"> • 5 lines available • Up to 75 characters are allowed per line • Case-sensitive 	<ul style="list-style-type: none"> • Final screen for each form • Do NOT use a question mark (?) or ampersand (&) or plus sign (+) or equal sign (=) or asterisk (*) or quotes (“ or ’) in a response • Generally, not a required data item field • An explanation keyed in the General Comments is required for any items coded with a r (refuse) or m (missing) code. A DCC edit report error will be generated for any item missing an explanation.
Special response codes	<p>d = don't know n = not applicable r = refused s = too sick to provide data m = missing m m year = missing date field (either the month and/or day missing) ? = query: temporarily missing</p>	<ul style="list-style-type: none"> • Data entry technician should key what is written on the form, not infer code • EXCEPTION is the data entry technician may need to key the query code (a question mark,?) if the data item is temporarily missing or illegible, in order to save the form data • Key 1 character code for any size field • Left-adjusted • See Appendices 11.4 and 11.5 for detailed use of codes

Appendix 11.4. Special data entry codes

CODE	DEFN	WHEN USED	INSTRUCTIONS*	IN DCC EDIT REPORT**
r	refuse	Participant refuses to answer the question or refuses to perform the procedure or test.	<ul style="list-style-type: none"> Write a brief explanation on the form indicating the reason for refusal of the procedure or to respond to the form questions or that the participant did not provide a reason. Make sure the reason is also data entered in General Comments. If the participant refuses to answer just a few questions, a refusal reason is not required, but helpful if the information is available. 	If the data form is audited and a note of explanation is missing from the form and/or database, the item will be noted in the audit report.
d	don't know	Participant says he/she does not know the answer.		Edit messages will not be sent regarding d codes.
n	not applicable	The item is not applicable.		Edit messages will not be sent regarding n codes.
s	too sick to provide data			Edit messages will not be sent regarding s codes.
m	missing	<ul style="list-style-type: none"> The information requested is missing or permanently not available. If information is missing but WILL become available, then code ?. 	<ul style="list-style-type: none"> Write a brief explanation on the form indicating the reason why the information is missing. Make sure that the data system operator keys the note. 	An edit message will be sent for each m code without a note in the database regarding why the item is missing. The purpose of the edit message is to verify that the information is truly missing.
m m year	partial missing date	The year of the date is known, but the day and/or month is missing.	<ul style="list-style-type: none"> When the year of the date is missing, use a single m to designate that the entire field is missing. Otherwise use an m within the date to designate the missing month and/or day: (e.g. m oct06 or m m 06). 	Edit messages will not be sent regarding partial date codes.

*Write one special code character in the space for the response even if the response space allows for more than one character (i.e., write **r** or **m**, NOT **rr** or **mmm**) and then press ENTER.

**If there are any questions about edits or an edit message is repeated despite having previously been responded to, fax the DCC a copy of the original edit sheet and the sheet with the repeat edit, together with a note describing the problem. The DCC will investigate it and correct the problem or give instructions on how to correct the problem.

Appendix 11.5. Use of ? (query) as data entry code

The data entry code for an item with an outstanding query is the question mark symbol, ?. This code should be used when data are temporarily missing (e.g., if handwriting cannot be deciphered and the person completing the form is not immediately available, or if lab results have not been received yet by the clinic).

Form items keyed as ? need to be edited (i.e., the ? item in the form needs to be resolved eventually once the data is available). All items coded with a ? will be listed in batch edit sheets prepared by the DCC until the ? is replaced with a response or other data entry code.

Please note that use of a question mark symbol (?) in a comment or specify item will result in an edit message. Instead of keying a question mark in these items, indicate uncertainty in a response by keying “possibly”, “quest”, “maybe”, etc.

Once the missing data item is available and the hard copy form has been updated and initialed, the electronic form record must be edited. To edit data, select *Data Entry* on the MAIN TASKS menu. Click *Change a data form* on the DATA ENTRY action menu to access previously keyed forms in CHANGE mode (see section 7.3).

Forms with edits or outstanding queries will be listed in the batch edit sheets prepared by the DCC until resolved, or can be listed by the clinic using the *Listings* task on the MAIN TASKS menu and clicking on ?s to display the Outstanding Queries report (see section 9.7).

Appendix 11.6. Resolution of data system error message

When occurs	Type of error message	Error resolution
Data entry error	<ul style="list-style-type: none"> Keyed value is not in correct format, or within the allowable range Required item is left blank Item keyed that should be skipped 	<ul style="list-style-type: none"> Keyed value is not same as the form response ► key the correct value Keyed value is same as the form response ► key the correct format, e.g. <ul style="list-style-type: none"> do NOT key a decimal point key leading and trailing zeroes key correct date format (ddmmmyy) where mmm is alphabetic if the “Other” response is checked, then <i>specify</i> should contain a response PIN numbers and a 1 for the study physician or clinical coordinator signature must be keyed (if signature is present) or ? if signature is absent Make sure that response to “Check all that apply” is indicated at the correct line If value is not within the available range and is verified to be correct, then contact DCC.
Data entry error	<ul style="list-style-type: none"> Value is inconsistent with another item in the 1st keying; example is date keyed for the “date form reviewed” is earlier than the “Visit date” recorded 	<ul style="list-style-type: none"> One of the 2 items is not the same as the responses written on the form or the form was not completed correctly. Key the correct value or a ?
Data entry error	<ul style="list-style-type: none"> Inconsistency between 2 keyings <p>NOTE: The value for the 1st keying will be displayed in the error message.</p>	<ul style="list-style-type: none"> Compare keyed responses and written form response and check formats If 1st keying is correct ► key correct value ► press ENTER If 2nd keying is correct ► press ENTER

Appendix 11.6. Resolution of data system error message

When occurs	Type of error message	Error resolution
Keyed item agrees with the response on the written data form, and that response is determined to be incorrect.	<ul style="list-style-type: none"> • A required item was left blank • An item was filled in that should have been skipped • A response was coded to an out of range value • Measurement units are coded, but the value is inconsistent with the specified scale • No signatures • A checked “Other” response does not have a <i>specify</i> response 	<ul style="list-style-type: none"> • Flag temporarily (e.g. with a post-it tab) the invalid or inconsistent response on the form • IF clinical coordinator is available ► have them correct the form ► key the correct response. • IF the coordinator is not available ► key a question mark (?) in order to complete data entry and save the record • NOTE: The data entry technician should NEVER change the form data and should only key corrected data that has been verified, corrected, and initialed with an explanation written on the form by an authorized person.
No error is found either in data entry or on the written form	Could be any of the error messages listed above	<ul style="list-style-type: none"> • Write down the error message and print screen • Key the query code (?) • Contact the DCC • May require a change in the data system checks - e.g., value ranges may need to be expanded
Within the data system	Data system or script error	<ul style="list-style-type: none"> • Write down the error message and print screen • Exit the data system • Contact the DCC • Once resolved, data system activities may resume

SOP III: GpCRC Web-Based Data Management System

11. Appendices

Gastroparesis Registry

RG - Registration

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

When: At first screening visit b.

Administered by: Clinical Coordinator.

Respondent: Patient.

Instructions: Use Flash Cards as instructed.

A. Center, patient and visit identification

1. Center ID: _____

2. Patient ID: 9521

3. Patient code XXX

4. Visit date: 15 - NOV - 06
day mon year

5. Visit code: b _____

6. Form & revision: r g 1

7. Study: Gastroparesis Registry 1

B. Consent

8. Has the patient signed the informed consent statement:

Yes (1) No (2)


C. Information about patient

9. Date of birth: 18 - AUG - 1970
day month year

Record 4-digit year for date of birth.

10. Age at last birthday: 36
years

11. Is the patient 18 or older:

Yes (1) No (2)


12. Gender:

Male (1)

Female (2)

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

Hispanic or Latino (1)

Not Hispanic, not Latino (2)

14. Racial category (show the patient Flash Card #2 and ask to pick the category or categories that describe 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)

15. Highest educational level achieved by patient (show the patient Flash Card #3 and ask 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)

Gastroparesis Registry

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

DRAFT

Purpose: To collect data on the psychosocial aspects of gastroparesis.

When: At screening visit b and follow-up visits f048, f096, f144, and f192.

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

Respondent: Patient, without help from spouse or family.

Instructions: The Clinical Coordinator should complete section A and attach a label to each of pages 2-4.

Screening: The patient should meet with the Clinical Coordinator, be trained in completion of the form, and then should complete pages 2-3. The Clinical Coordinator should review the completed form for missing responses and resolve any problems before the patient leaves the clinical center. Pages 1 and 4 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B.

Follow-up: Pages 2-3 should be mailed to the patient 2 weeks prior to the scheduled study visit with instructions to complete the form at home and 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 and 4 should be reattached to pages 2-3 and the Clinical Coordinator should complete section B. Fill in item 4 with the date of the study visit.

Scoring: The Y-1 and Y-2 scores should be calculated using the scoring key on page 4. Only the items on page 1 are keyed to the Gastroparesis Registry. Staple pages 1-4 together at the close of the assessment.

A. Clinic, visit, and patient identification

1. Center ID: _____
2. Patient ID: 9521
3. Patient code: X X X
4. Visit date:
17 - NOV - 06
day mon year
5. Visit code: b _____
6. Form & revision: s e 0
7. Study: Gastroparesis Registry 1

B. Administrative information

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

8. Scoring
- a. Form Y-1 (sum of weights for items 1-20)
32
(20-80)
- b. Form Y-2 (sum of weights for items 21-40)
32
(20-80)
9. Examiner
- a. Name (please print):
R. Examiner
- b. Signature:

10. Clinical Coordinator
- a. PIN: 903
- b. Signature:
C. Coordinator
11. Date form reviewed:
17 - NOV - 06
day mon year

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-1

Affix label here

Pt ID: 9521
 Patient code: XXX
 Visit code: b

DIRECTIONS:

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

VERY MUCH SO
 MODERATELY SO
 SOMEWHAT
 NOT AT ALL

- 1. I feel calm 1 2 3 4
- 2. I feel secure 1 2 3 4
- 3. I am tense 1 2 3 4
- 4. I am strained 1 2 3 4
- 5. I feel at ease 1 2 3 4
- 6. I feel upset 1 2 3 4
- 7. I am presently worrying over possible misfortunes 1 2 3 4
- 8. I feel satisfied 1 2 3 4
- 9. I feel frightened 1 2 3 4
- 10. I feel comfortable 1 2 3 4
- 11. I feel self-confident 1 2 3 4
- 12. I feel nervous 1 2 3 4
- 13. I am jittery 1 2 3 4
- 14. I feel indecisive 1 2 3 4
- 15. I am relaxed 1 2 3 4
- 16. I feel content 1 2 3 4
- 17. I am worried 1 2 3 4
- 18. I feel confused 1 2 3 4
- 19. I feel steady 1 2 3 4
- 20. I feel pleasant 1 2 3 4

SELF-EVALUATION QUESTIONNAIRE - STAI Form Y-2

Affix label here

Pt ID: 9521
 Patient code: XXX
 Visit code: b

DIRECTIONS:

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

ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS

- 21. I feel pleasant 1 2 **3** 4
- 22. I feel nervous and restless **1** 2 3 4
- 23. I feel satisfied with myself 1 2 **3** 4
- 24. I wish I could be as happy as others seem to be 1 **2** 3 4
- 25. I feel like a failure **1** 2 3 4
- 26. I feel rested 1 2 **3** 4
- 27. I am "calm, cool, and collected" 1 **2** 3 4
- 28. I feel that difficulties are piling up so that I cannot overcome them **1** 2 3 4
- 29. I worry too much over something that really doesn't matter **1** 2 3 4
- 30. I am happy 1 2 **3** 4
- 31. I have disturbing thoughts **1** 2 3 4
- 32. I lack self-confidence 1 **2** 3 4
- 33. I feel secure 1 2 **3** 4
- 34. I make decisions easily 1 2 **3** 4
- 35. I feel inadequate 1 **2** 3 4
- 36. I am content 1 2 3 **4**
- 37. Some unimportant thought runs through my mind and bothers me **1** 2 3 4
- 38. I take disappointments so keenly that I can't put them out of my mind **1** 2 3 4
- 39. I am a steady person 1 2 **3** 4
- 40. I get in a state of tension or turmoil as I think over my recent concerns and interests **1** 2 3 4

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

Affix label here

Pt ID: 9521

Patient code: XXX

Visit code: b

DIRECTIONS:

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

VERY MUCH SO
 MODERATELY SO
 SOMEWHAT
 NOT AT ALL

ALMOST ALWAYS
 OFTEN
 SOMETIMES
 ALMOST NEVER

Form Y-1

Form Y-2

1.	4	3	2	1
2.	4	3	2	1
3.	1	2	3	4
4.	1	2	3	4
5.	4	3	2	1
6.	1	2	3	4
7.	1	2	3	4
8.	4	3	2	1
9.	1	2	3	4
10.	4	3	2	1
11.	4	3	2	1
12.	1	2	3	4
13.	1	2	3	4
14.	1	2	3	4
15.	4	3	2	1
16.	4	3	2	1
17.	1	2	3	4
18.	1	2	3	4
19.	4	3	2	1
20.	4	3	2	1

21.	4	3	2	1
22.	1	2	3	4
23.	4	3	2	1
24.	1	2	3	4
25.	1	2	3	4
26.	4	3	2	1
27.	4	3	2	1
28.	1	2	3	4
29.	1	2	3	4
30.	4	3	2	1
31.	1	2	3	4
32.	1	2	3	4
33.	4	3	2	1
34.	4	3	2	1
35.	1	2	3	4
36.	4	3	2	1
37.	1	2	3	4
38.	1	2	3	4
39.	4	3	2	1
40.	1	2	3	4

Gastroparesis Registry

LR - Laboratory Results

DRAFT

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

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

Administered by: Study Physician and Clinical Coordinator.

Instructions: Laboratory test results may be obtained from chart review. Complete tests as needed (repeat test if archival test is not within the required time window). The window for each test is specified next to the date of blood draw. Use a calculator if you need to convert units to match the units specified on this form. Please note that the units 10^3 cells/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. 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: 95213. Patient code: XXX4. Date of visit (date form was initiated):
15 - NOV - 06
day mon year5. Visit code: b _____6. Form & revision: 1 r 07. Study: Gastroparesis Registry 1

B. Etiologic tests

8. Was blood drawn for ANA, Scl-70, CRP, and SPEP at this visit:

Yes () No ()

14. _____

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

30 - OCT - 06
day mon year

Date must be within the required time window: within one year of the registration or in the time window for the follow-up visit (check the patient's Registry visit time window guide). Optional during follow-up visits.

10. Antinuclear antibody (ANA):

Positive ()Negative ()

11. _____

a. If positive, titer of ANA:

1 / _____

11. Scleroderma antibody (Scl-70):

Positive ()Negative ()

12. _____

a. If positive, Scl-70: _____

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

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

001.2
mg/dL

13. Serum protein electrophoresis (SPEP)

a. Albumin: 03.7
g/dLb. Alpha-1-Globulin: 0.4
g/dLc. Alpha-2-Globulin: 0.8
g/dLd. Beta-Globulin: 0.7
g/dLe. Gamma-Globulin: 1.3
g/dLf. Total protein: 07.8
g/dL

Patient ID: 9521

C. Hematology

14. Was blood drawn for hematology panel at this visit:

Yes (1) No (2)
23.

15. Date of blood draw for hematology panel:

15 - NOV - 06
day mon year

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

16. Hemoglobin:

14.2
g/dL

17. Hematocrit:

42.0
%

18. Erythrocyte sedimentation rate:

018
mm/hr

19. White blood cell count (WBC):

005.9
10³ cells/ μ L or 10⁹ cells/L

20. Platelet count:

180,000
cells/ μ L

21. Prothrombin time (PT):

12.3
sec

22. Partial thromboplastin time (PTT):

34.6
sec

D. Chemistries and HbA1c

23. Was blood drawn for chemistry panel at this visit:

Yes (1) No (2)
33.

24. Date of blood draw for chemistries:

15 - NOV - 06
day mon year

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

25. Sodium:

140
mEq/L

26. Potassium:

04.0
mEq/L

27. Chloride:

107
mEq/L

28. Bicarbonate:

25.0
mEq/L

29. Calcium:

09.1
mg/dL

30. Blood urea nitrogen (BUN):

13
mg/dL

31. Creatinine:

00.7
mg/dL

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

Yes (1) No (2)
EKG

32. Serum glucose:

108
mg/dL

33. Was blood drawn for HbA1c at this visit:

Yes (1) No (2)
36.

34. Date of blood draw for HbA1c:

15 - NOV - 06
day mon year

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

35. HbA1c:

05.7
%

E. Hepatic panel

36. Was blood drawn for hepatic panel at this visit:

(Yes) (No)
() ()
42.

37. Date of blood draw for hepatic panel:

15 - NOV - 06
day mon year

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

38. Bilirubin (total):

00.7
mg/dL

39. Aspartate aminotransferase (AST):

032
U/L

40. Alanine aminotransferase (ALT):

045
U/L

41. Alkaline phosphatase:

060
U/L

F. Administrative information

42. Study Physician PIN:

901

43. Study Physician signature:

S. Physician

44. Clinical Coordinator PIN:

903

45. Clinical Coordinator signature:

C. Coordinator

46. Date form reviewed:

17 - NOV - 06
day mon year

Gastroparesis Registry

PE - Physical Examination

DRAFT

Purpose: Record detailed physical exam findings.

When: Screening visit b and follow-up visits f016, f032, f048, f064, f080, f096, f112, f128, f144, f160, f176, and f192.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient.

Instructions: Details of the protocol for height, weight, waist and hip measurements are found in Gastroparesis Registry SOP, Part I. In brief: Height, weight, waist and hips all should be measured with the patient standing and wearing light clothing. Shoes should be removed for height and weight measures. Measure the waist around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest part of the costal margin in the mid axillary line. Measure the hips at the fullest part.

A. Center, patient, and visit identification

1. Center ID: _____

2. Patient ID: 95213. Patient code: XXX4. Visit date: 15 NOV 06
day mon year5. Visit code: b _____6. Form & revision: pe 07. Study: Gastroparesis Registry 1

B. Measurements

8. Height (*shoes off*)a. Height: 166.4b. Units:
Inches ()
Centimeters (✓)9. Weight (*shoes off*)a. Weight: 058.9b. Units:
Pounds ()
Kilograms (✓)10. Waist (*standing, at midpoint between highest point of iliac crest and lowest part of costal margin*)a. Circumference: 078.7b. Units:
Inches ()
Centimeters (✓)11. Hip (*standing, at fullest part of the hips*)a. Circumference: 091.4b. Units:
Inches ()
Centimeters (✓)12. Temperature (*oral*)a. Degrees: 098.5b. Scale:
Fahrenheit (✓)
Centigrade ()

13. Blood pressure

a. Systolic: 124
mmHgb. Diastolic: 073
mmHg

14. Resting radial pulse:

081
beats/minute

15. Respiratory rate:

22
breaths/minute

Patient ID: 9521

C. Examination findings

16. Chest and lungs:

Normal (1)
Abnormal (2) **17.**

specify

17. Heart:

Normal (1)
Abnormal (2) **18.**

specify

18. Abdomen:

Normal (1)
Abnormal (2) **20.**

19. Abdomen abnormality (check all that apply)

- a. Distention: (1)
- b. Tympany: (1)
- c. Succussion splash: (1)
- d. Tenderness: (1)
- e. Organomegaly: (1)
- f. Other (specify): (1)

specify

20. Liver and spleen:

Normal (1)
Abnormal (2) **21.**

specify

21. Other abnormalities noted:

Yes (1) No (2)
22.

specify other abnormalities

D. Administrative information

22. Study Physician PIN: 901

23. Study Physician signature:
S. Physician

24. Clinical Coordinator PIN: 903

25. Clinical Coordinator signature:
C. Coordinator

26. Date form reviewed:
16 - NOV - 06
day mon year

Gastroparesis Registry

EG - Upper Endoscopy Documentation

Purpose: To document the results of the upper gastrointestinal endoscopy to determine patient eligibility.

When: Screening visit b. The upper gastrointestinal endoscopy procedure must have been performed within 12 months prior to enrollment.

Administered by: Study Physician and Clinical Coordinator.

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.

A. Center, patient, and visit identification

1. Center ID: _____
2. Patient ID: 9521
3. Patient code: X X X
4. Date form is initiated:
17 - NOV - 06
 day mon year
5. Visit code: b _____
6. Form & revision: e g 1
7. Study: Gastroparesis Registry 1

B. Upper endoscopy information

8. Date of upper endoscopy:
31 - OCT - 06
 day mon year
Date must be within 12 months prior to the registration date. If not, STOP. The upper endoscopy must be repeated.
9. Reason(s) for the procedure (*check all that apply*):
- a. Gastroparesis symptoms/rule out obstruction: ()
- b. Anemia: ()
- c. Abdominal pain: ()
- d. Gastrostomy tube: ()
- e. Other (*specify*): ()
- _____ other specify

C. Endoscopic findings

10. Normal esophagus: (Yes) (No)
11. _____ ()
- (*If no, check all that apply*):
- a. Esophagitis: ()
- b. Barrett's Esophagus: ()
- c. Hiatal hernia: ()
- d. Other esophageal finding (*specify*): ()
- _____ other specify
11. Normal stomach: (Yes) (No)
13. _____ ()
- (*If no, check all that apply*):
- a. Gastritis: ()
- b. Ulcer: ()
- c. Polyp(s): ()
- d. Mass: ()
- e. Retained food: ()
- f. Pyloric stenosis: ()
- g. Other gastric findings, excluding any gastric surgery (*specify*): ()
- _____ other specify

12. Surgical change(s) found in stomach: Yes () No ()

- (If yes, check all that apply):
a. Total resection: ()
b. Billroth I: ()
c. Billroth II: ()
d. Roux-en-Y gastrojejunostomy: ()
e. Other pyloroplasty or antrectomy: ()
f. Prior fundoplication: ()
g. Other subtotal resection: ()
h. Other gastric surgery (specify): ()

other specify

13. Normal duodenum: Yes () No ()

- (If no, check all that apply):
a. Duodenitis: ()
b. Ulcer: ()
c. Polyp(s): ()
d. Mass: ()
e. Other duodenal finding (specify): ()

other specify

D. Histologic findings

14. Esophageal histology done: Yes () No ()

15. Esophageal histology normal: Yes () No ()

- (If no, check all that apply):
a. Esophagitis: ()
b. Barrett's Esophagus: ()
c. Other (specify): ()

other specify

16. Gastric histology done: Yes () No ()

17. Gastric histology normal: Yes () No ()

- (If no, check all that apply):
a. Chemical gastritis: ()
b. Atrophic gastritis: ()
c. Ulcer: ()
d. Eosinophilic gastroenteritis: ()
e. Fundic gland retention polyp: ()
f. Adenomatous polyp: ()
g. Helicobacter pylori infection: ()
h. Other (specify): ()

other specify

18. Duodenal histology done: Yes () No ()

19. Duodenal histology normal: Yes () No ()

- (If no, check all that apply):
a. Duodenitis: ()
b. Ulcer: ()
c. Celiac sprue: ()
d. Other (specify): ()

other specify

E. Other comments

20. Other comments concerning upper endoscopy procedure or results:

Yes () No (✓)

21.

a. Other comments:

21. Was there any other endoscopic or histologic finding that in the opinion of the Study Physician would explain the patient's symptoms or characterize the patient as ineligible:

Yes () No (✓)

22.

If Yes, specify:

F. Administrative information

22. Study Physician PIN: 901

23. Study Physician signature: S. Physician

24. Clinical Coordinator PIN: 903

25. Clinical Coordinator signature: C. Coordinator

26. Date form reviewed: 17 - NOV - 06
 day mon year

Gastroparesis Registry

EN - Registry Enrollment

DRAFT

Purpose: • Check eligibility for Gastroparesis Registry.
 • Record reasons for ineligibility for patients found to be ineligible.

When: Visit e.

Administered by: Study Physician and Clinical Coordinator.

Respondent: Patient and Clinical Coordinator.

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

A. Center, patient, and visit identification

- 1. Center ID: _____
- 2. Patient ID: 9521
- 3. Patient code: XXX
- 4. Visit date (date this form is initiated):
20 - NOV - 06
day mon year
- 5. Visit code: e _____
- 6. Form & revision: e n 0
- 7. Study: Gastroparesis Registry 1

B. Exclusions

8. Do any of the patient's assessments show evidence of these medical exclusions:

- a. Pyloric or intestinal obstruction:
 Yes () No ()
- b. Active inflammatory bowel disease:
 Yes () No ()
- c. Eosinophilic gastroenteritis:
 Yes () No ()

d. Neurologic conditions such as increased intracranial pressure, space occupying or inflammatory/infectious lesions:

Yes () No ()

e. Acute liver failure:

Yes () No ()

f. Advanced liver disease (Child's B or C):

Yes () No ()

g. Acute renal failure:

Yes () No ()

h. Untreated chronic renal failure (serum creatinine > 3.0 mg/dL):

Yes () No ()

i. Total or subtotal gastric resection:

Yes () No ()

j. Any other plausible structural or metabolic cause:

Yes () No ()

Patient ID: 9521

G. Administrative information

17. Study Physician PIN: 901

18. Study Physician signature:
S. Physician

19. Clinical Coordinator PIN: 903

20. Clinical Coordinator signature:
C. Coordinator

21. Date form reviewed:
20 - NOV - 06
day mon year

GpCRC

*Gastroparesis
Clinical Research Consortium*

Gastroparesis Registry

Standard Operating Procedures

**Part IV: Standards of Care for Patients
with Gastroparesis**

12 October 2006

GpR SOP Part IV: Standards of Care

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GpR SOP Part IV: Standards of Care

1. Introduction

The purpose of this document is to articulate a uniform set of practices to be applied by investigators in the Gastroparesis Clinical Research Consortium (GpCRC) in the evaluation and care of patients with gastroparesis that are entered in the Gastroparesis Registry (GpR). These standards were developed so that patients with gastroparesis will be evaluated uniformly before being placed in the GpR. Once patients are in the GpR, they will be treated in a generally standard fashion across clinical centers, thereby reducing the extent to which evaluation and care at a particular center will influence diagnosis, treatment, and outcome. In addition, these standards of care are written to delineate the tests and procedures used for routine clinical care of patients with gastroparesis. These standards of care were derived by expert opinion as expressed by prior documents by the American Gastroenterological Association and the American Motility Society and refined by the consensus of investigators of the GpCRC. Every effort will be made to adhere to these standards of care for each patient. Patients in the GpR will qualify for a variety of gastroparesis treatment protocols.

GpR SOP Part IV: Standards of Care

2. New patient with possible gastroparesis

Each patient will be evaluated for gastroparesis based on the following:

1. Presence of appropriate symptoms/signs of gastroparesis for at least 12 weeks of the past year.
2. Gastric emptying scintigraphy using a 4 hour low fat Egg Beaters meal as described by Tougas et al 2000¹. Delayed gastric emptying using 4 hour scintigraphy is considered with gastric retention at 2 hours postprandially to be >60% or at 4 hours to be >10%. General practice is to try to stop medications known to delay or accelerate gastric emptying for 3 days prior to the gastric emptying test.
3. Exclusion of gastrointestinal obstruction—generally performed with a careful history and physical examination, laboratory testing, radiographic evaluation, and upper endoscopy.

Although there are general guidelines for the evaluation of patients with gastroparesis^{2,3}, the exact evaluation of a patient may differ depending on the individual case characteristics.

Initial evaluation of a patient with suspected gastroparesis

History

Gastric symptoms: dominant and associated symptoms (nausea, vomiting, pain/discomfort, early satiety, fullness, bloating), duration, frequency, onset (abrupt vs. insidious), course, precipitating/relieving factors. Nature of symptoms: cyclic vs non-cyclic. If cyclic; are cycles regular or not.

Extragastric symptoms: Other GI symptoms (diarrhea, constipation), anorexia, weight loss, dehydration, orthostatic symptoms, poor glycemic control in diabetics

History of infectious disorders with resultant chronic upper GI motility symptoms.

Assessment of nutritional status

Dietary intolerance

Other disorders and surgeries—especially those that might relate to symptoms of gastroparesis (e.g. diabetes, collagen vascular disease, endocrine diseases such as hypothyroidism, peptic ulcer surgery, fundoplication, surgeries involving gastric nerve plexi – as for neurofibromatosis)

Symptoms or diagnosis of overlap syndromes: migraine headaches, fibromyalgia, interstitial cystitis, endometriosis, depression.

Hospitalizations/emergency room visits for intractable symptoms (frequency/yr)

Other medical problems

Prior surgeries

Family history of gastroparesis, GI motility disorders, overlap syndromes

Review of current medications

Clinical response to present and past medications given for patient's symptoms: acid suppressants, antiemetics, prokinetics, tricyclic anti-depressants, analgesics

GpR SOP Part IV: Standards of Care

2. New patient with possible gastroparesis

Physical examination

Vital Signs: blood pressure, pulse, temperature, weight, height, body mass index (BMI)

Optional: Orthostatic vital signs

Abdominal examination: visible distention, tympany, succussion splash, tenderness, organomegaly

Rectal examination with assessment of occult fecal blood

Documentation of recent gynecologic exam by internist or gynecologist

Laboratory tests

Complete blood count

Complete metabolic panel, including electrolytes, glucose, creatinine, total protein, albumin, calcium, liver chemistries

Magnesium

Thyroid function tests, thyroid stimulating hormone

Optional tests (obtained in part on the particular patient):

Blood tests:

prothrombin time, partial thromboplastin time and other hypercoagulable markers, HbA_{1c}, erythrocyte sedimentation rate, anti-nuclear antibody, C-reactive protein, pregnancy test, tissue transglutaminase antibody, fasting cortisol, paraneoplastic antibody panel (e.g. anti-Hu, SPEP) Amylase and/or lipase

Urinalysis (if clinically indicated)

Electrocardiogram (if considering treatment with domperidone, desipramine)

Radiology

Abdominal obstruction series, if suggested by history (profound pain, bloating, or vomiting) or physical examination (distention, tympany)

Abdominal right-upper quadrant ultrasound to rule out gallbladder, liver, and pancreatic disease, if suggested by history, physical examination (RUQ pain or tenderness), or laboratory findings (elevated liver chemistries)

Endoscopy

Upper endoscopy (must have been done within 12 months prior to entering the registry).

Esophageal, gastric and duodenal biopsies may be obtained (if indicated by history, physical examination (associated bloating, diarrhea, or family history of celiac disease), or laboratory findings (unexplained microcytic anemia))

GpR SOP Part IV: Standards of Care

2. New patient with possible gastroparesis

Nuclear medicine

Gastric emptying scintigraphy (Solid phase - % retention at 0, 0.5, 1, 2, 3, 4 hrs). Must have been done at a GpCRC clinical center within 6 months prior to enrollment. Required standardized test meal outlined in GpR SOP Part I: Clinical Center Operations, section 6.2 Gastric Emptying Scintigraphy.

Other tests which may be obtained

Electrogastrogram by fast fourier and/or signal averaging analysis

With meal – water load, Ensure, egg sandwich

Antroduodenal manometry (to exclude associated small intestinal dysmotility)

Small bowel radiographic examination (to exclude mechanical lesions of the small intestine):

Small Bowel Follow-Through, Enteroclysis, Computer Tomographic Enterography

Small intestinal transit testing: Scintigraphy, small intestinal barium series, lactulose breath testing

Hydrogen breath testing (to exclude small intestinal bacterial overgrowth)

Sitzmarker study, in patients with lower bowel complaints

Anal manometry and/or anal EMG, balloon evacuation

Urodynamic evaluation, in patients with urinary symptoms

Psychometric and quality of life measures, including

Gastroparesis Cardinal Symptom Index, pain measure, anxiety/depression measure, SF-36, health resource measure, eating attitudes test or similar measure

Autonomic testing – standard cholinergic and adrenergic or 24 hour Holter for heart rate variability, giving an assessment of high and low frequency power

Treatment

- The general principles for treatment of symptomatic gastroparesis are to (1) correct fluid, electrolyte, and nutritional deficiencies; (2) identify and rectify the underlying cause of gastroparesis if possible; and (3) reduce symptoms⁴.
- The patient's medication list should be reviewed to eliminate drugs that might exacerbate the underlying dysmotility disorder or prevent the beneficial actions of a prokinetic agent.
- Diabetic patients should strive for reasonable glycemic control to minimize any inhibitory effects of hyperglycemia on gastric emptying. This is often performed with the patient's endocrinologist or internist.
- Primary treatment of gastroparesis includes dietary manipulation and the administration of antiemetic and/or prokinetic therapies.
- A baseline gastroparetic instruction sheet will be given to the patients with suggestions to follow. Additional treatments for refractory symptoms or if pain is a dominant symptom may include the use of tricyclic anti-depressants and/or analgesic medications. Occasionally newer agents (Cymbalta or Lyrica) are tried on an off label basis.
- For relatively mild disease, dietary modifications and intermittent administration of a low-dose antiemetic or prokinetic agent may provide satisfactory control of symptoms.

GpR SOP Part IV: Standards of Care

2. New patient with possible gastroparesis

- Patients with more severe manifestations of gastroparesis, such as refractory vomiting, pronounced dehydration, or chaotic glucose control, might require hospitalization, intravenous hydration, nasogastric suction to decompress the stomach, insulin for blood glucose control, and/or intravenous administration of antiemetic and prokinetic agents.
 - Consideration of surgically or endoscopically placed enteral tubes for feeding and/or venting
 - Surgical options (gastric electrical stimulation, jejunostomy placement) are considered for persistently refractory cases.
 - Other medications can be given for related overlap symptoms, such as for migraine headaches.
-

GpR SOP Part IV: Standards of Care

3. Follow-up visits

The frequency of follow-up visits depends on the need for diagnostic testing, the severity of symptoms and complications of gastroparesis, responses to therapy, and complications of prescribed treatments.

Patients may be seen frequently when undergoing initial evaluation, perhaps more often than once monthly depending on the clinical course.

Patients with stable, controlled symptoms should be evaluated periodically (generally every 3-6 months depending on clinical and geographic factors) by their gastroenterologist for surveillance to evaluate for changes in clinical course or subtle toxicities from medication therapies (e.g. dystonias from prokinetic/antiemetic treatments). These surveillance visits should include an interim history, review of symptoms, updated medication list, physical examination, laboratory work, and discussion of adherence to the standard of care recommendations.

Items for documentation

History

- Review of disease course
- Assessment of current symptoms
- Assessment of nutritional status
- Other disorders and surgeries
- Review of current medications
- Response to any treatment given since last visit
- Psychosocial history – document any changes

Physical examination

- Vital Signs: Complete Blood Count, pulse, weight
- Optional: orthostatic vital signs
- Abdominal examination: tenderness, succussion splash

Laboratory tests

- If needed: Complete Blood Count, complete metabolic panel, Magnesium, Thyroid Function Test, amylase/lipase
- Optional: Erythrocyte Sedimentation Rate, C-Reactive Protein, urinalysis, Electrocardiogram
- Optional: Abdominal obstruction series

Treatment considerations

Discuss present treatment. Consider additional treatment with, if needed, hydration, nutrition, antiemetic agents, prokinetic agents, analgesic agents, tricyclic agents, botulinum toxin, gastric electric stimulation. Consider home IV medications if symptoms particularly severe and/or cyclic.

GpR SOP Part IV: Standards of Care

4. Dietary and nutritional recommendations

Gastroparesis, or paralysis of the stomach, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions, especially in people with diabetes. However, in many individuals with gastroparesis, the cause of the disorder is not known. It is more common in women and can have a major impact on quality of life.

The general principles for treating symptomatic gastroparesis involve several strategies. First, attempts are made to correct fluid and nutritional deficiencies that may have occurred from chronic nausea and vomiting, and/or the inability to eat normally. Second, treatments are given for the unpleasant symptoms that accompany gastroparesis. Third, the underlying cause of gastroparesis, such as diabetes, thyroid disorders, etc., is treated if possible. The treatment of patients with gastroparesis generally relies on dietary modifications, medications that enhance gastric emptying, and medications that reduce nausea and vomiting.

A number of dietary recommendations have been developed based on the understanding of normal stomach emptying of different types of foods. These dietary recommendations are likely to be of greatest benefit to those with mild to moderate disease, but are also tried in patients with more severe gastroparesis to complement other medical treatments. It is recommended that anyone with gastroparesis, but especially those with other medical problems such as diabetes or kidney disease, seek dietary counseling with a dietician to help individualize nutrition therapy and maximize nutritional benefits.

Basic dietary guidelines:

- Small, frequent meals. Reducing the meal size reduces the distention of the stomach from the meal. By eating smaller meals, patients may not feel as full or bloated and the stomach may empty faster. With the reduction in meal size, increasing the number of meals to 4-6 per day is needed to maintain adequate nutritional intake.
- Avoid foods high in fat. Fat can delay emptying of the stomach. Eating less fat-containing foods will decrease the amount of time food stays in the stomach. However, fat-containing liquids, such as milkshakes, may be tolerated and provide needed calories.
- A diet low in fiber is suggested. Fiber delays gastric emptying. In addition, fiber may bind together and cause a blockage of the stomach, called a bezoar in some patients. Examples of high fiber foods that should be avoided include oranges, berries, green beans, potato peels, apples, sauerkraut, and Brussel sprouts. Fiber supplements for treatment of constipation should also be discontinued if possible.

GpR SOP Part IV: Standards of Care

4. Dietary and nutritional recommendations

- Chew food well before swallowing. Patients should avoid foods that may not easily be chewed such as broccoli, corn, popcorn, nuts, and seeds. Solid food in the stomach does not empty well. Dental problems, such as missing or broken teeth, may lead to poorly chewed food; this may add to the problem of inadequate breakdown of food into smaller particles in the stomach for passage into the small intestine for absorption.
- Taking fluids throughout the meal and sitting upright or walking for 1-2 hours after meals may help in the emptying of the meal from the stomach.
- A daily multivitamin/mineral supplement can be taken if dietary intake is inadequate.

If these measures are ineffective, the patient may be advised to consume the bulk of their meals as semi-solids or liquids, such as puréed foods or soups. Stomach emptying of liquids is often normal in patients with gastroparesis. Calorie-containing drinks, such as Hawaiian Punch or Hi C, provide fluid and calories, hence are better than water alone. Some options while on a liquid diet include milk, instant breakfast, milkshakes, yogurt, puddings, custard, cereals, and smoothies. To meet the nutritional needs of patients, it may be necessary to supplement the diet with a commercially available liquid nutrient preparation that is low in fiber such as Ensure, Boost, or even baby foods. Blenderized foods prepared by the patient may also be used as a liquid nutrient source. Any food can be blenderized; solid foods will need to be thinned with some type of liquid, such as broth, milk, juice, water. The blender should be cleaned well after each use.

There are quite a few medications that can delay stomach emptying. Check if any of the medications the patient is taking could be slowing down the stomach emptying.

If the gastroparesis is due to diabetes, an important goal is to achieve or maintain good glucose control. This is achieved more easily by frequent monitoring of blood sugar levels and adjustment of insulin. Keeping the blood sugar under control may help stomach emptying. Consult your endocrinologist if the patient's blood sugar runs > 200 mg/dL on a regular basis.

Patients with kidney disease need to follow additional dietary advice. The dietary restrictions will depend on nephrologist's assessment. Adequate protein is needed for nourishment, but too much may increase a waste product called urea that kidneys may not be able to get rid of. High sodium (salt) intake can increase blood pressure and fluid retention. Restriction of potassium varies depending on the stage of kidney disease. Generally, one should avoid high potassium foods such as bananas, oranges, kiwi, leafy greens, and broccoli. Kidneys may not be able to remove phosphorous from the blood. High phosphorous foods include dried beans, peas, nuts, and liver.

Patients with chronic symptoms of gastroparesis, despite these attempts at dietary intervention and medication, may develop dehydration and malnutrition. Occasionally, patients need an alternative method to obtain fluid and nutrition. This might involve delivering fluids and nutrients directly into the small intestine, bypassing the stomach, using a jejunostomy tube. In severe cases, intravenous fluids and nutrition may need to be provided.

GpR SOP Part IV: Standards of Care

4. Dietary and nutritional recommendations

Table 1: Dietary Recommendations for Gastroparesis

- Eat smaller, more frequent meals
- Eat less fatty foods
- Avoid fiber
- Avoid foods that cannot be chewed well.

Table 2: Additional dietary recommendations for gastroparesis

- Liquid nutrients are better tolerated over solid food
- Good glucose control in patients with diabetes (aim for blood sugars < 180 mg/dl)
- Avoid medications that can delay stomach emptying such as:
 - Aluminum-containing antacids (Amphojel)
 - Narcotic pain medications (Percocet, Tylenol #3, Tylox, Oxycontin, and others)
 - Anticholinergic agent (Bentyl, Levsin, Elavil, and others)
 - Bulk-forming agents (Metamucil, Perdiem, Fibercon, and others)

Table 3: Foods that are encouraged

- Breads, cereals, crackers, ground or pureed meats
- Vegetables – cooked and, if necessary, blenderized/strained
- Fruits – cooked and, if necessary, blenderized/strained
- Juices, beverages, milk products, if tolerated

Table 4: High fiber foods that should be avoided in gastroparesis

- Fruits - apples, berries, coconuts, figs, oranges, persimmons,
- Vegetables - Brussel sprouts, green beans, green peas, lettuce, potato peels, sauerkraut
- Bran/whole grain cereals
- Nuts and seeds
- Legumes/dried Beans – baked beans, lentils, soy beans

GpR SOP Part IV: Standards of Care

4. Dietary and nutritional recommendations**A sample diet for patients with gastroparesis: sample meal plan for 6 small meals**

Breakfast	1 cup cream of wheat cereal ½ cup skim milk ½ cup grape juice 1 scrambled egg
Snack	10 ounces of instant breakfast with skim milk
Lunch	½ cup vegetable soup ½ turkey sandwich ½ cup applesauce ½ cup milk 1 tablespoon mayonnaise
Snack	10 ounces banana shake made with 1 plain or vanilla yogurt, milk and sugar
Dinner	2-3 ounces baked chicken or fish ½ cup mashed potatoes 1 teaspoon margarine ½ cup spinach ½ cup milk ½ cup fruit cocktail
Snack	½ cup pudding, custard or gelatin

GpR SOP Part IV: Standards of Care

5. References

1. Tougas G, Eaker EY, Abell TL, Abrahamsson H, Boivin M, Chen J, Hocking MP, Quigley EM, Koch KL, Tokayer AZ, Stranghellini V, Chen Y, Huizinga JD, Ryden J, Bourgeois I, McCallum RW. Assessment of gastric emptying using a low fat meal: establishment of international control values. *Am J Gastroenterol* 2000;95:1456-62.
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