

WCMC Protocol Summary

Protocol Number: 1512016797A002**Status:** Archived**Expiration Date:** 05/18/2017**Last Approval Date:****Investigator:** Jesudian, Arun B.**Protocol Description****Review Type:** Initial Protocol (Full Board or Expedited or Exempt)**Application Date:** 03/14/2017**Title:** A retrospective review of gastric emptying in cirrhotic subjects.**Required Summary:**

Recent data have demonstrated that impaired gastrointestinal (GI) motility is common in cirrhotic subjects. Observed abnormalities in cirrhosis include altered gastric sensorimotor function, delayed gastric emptying, and decreased small bowel motility. Gastric emptying in particular is severely prolonged in cirrhotic subjects, and this finding likely accounts for the GI symptoms of bloating and early satiety commonly reported by this population. Cirrhotic subjects routinely undergo upper endoscopy as screening for esophageal and gastric varices for primary prevention of variceal hemorrhage, a significant cause of morbidity/mortality in this population. Preparation for upper endoscopy involves the subject abstaining from food intake for a total of 8 hours prior to the procedure to ensure an empty stomach. The diagnostic yield of an upper endoscopy, in terms of identifying varices and other mucosal changes associated with portal hypertension in cirrhosis, depends on the ability of the endoscopist to completely visualize the stomach. Retained food at the time of endoscopy can significantly impair this yield. In addition, having food present in the stomach increases the risk for procedure-related complications such as scope-induced trauma or perforation, or aspiration of gastric contents during anesthesia. As cirrhotic subjects are at risk for delayed gastric emptying and routinely require upper endoscopy, they might be at increased risk of retained gastric contents at endoscopy compared to noncirrhotic subjects. The aim of this study is to retrospectively identify the incidence of retained food at the time of endoscopy in age-matched cirrhotic vs. noncirrhotic subjects. We will also identify the miss rate for endoscopic findings and the procedure complication rate when retained food is present in cirrhotic subjects.

Performance Sites

Type	Site	Address
Performing Organization	Weill Medical College of Cornell University	Grants & Contracts 1300 York Avenue, Box 89 New York NY - 10021 USA

Investigators

Person Name	Primary Title	Directory Title	Units	Affiliate	Training Flag
Jesudian, Arun B.	Assistant Professor	M.D.	Medicine	PI - Responsible for Entire Protocol	N

WCMC

Protocol #: 1512016797A002

Investigator: Jesudian, Arun B.

Expiration

Date: 05/18/2017

Last Approval Date:

Investigators

Person Name	Primary Title	Directory Title	Units	Affiliate	Training Flag
Cohen-Mekelburg, Shirley		M.D.	Medicine		N
Snell, David		M.D.	Medicine	Collect demographics, Evaluate Inclusion/Exclusion Criteria and Medical History, Perform other study specific interventions, Record Concomitant Medications, Data Analysis	N

Administrative Contact

Type	Name	Comments
Administrator	Snell, David	

Funding Source

Type	Name/Title
Department/Division	Gastroenterology & Hepatology

Actions

Description	Comments	Action Date
Archived	Archived	03/14/2017

Amendment/Renewal Summary

Summary	Editable Modules
Change administrative contact to David Snell. Allow for editing. Extend expiration date to 12/18/2017	

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Subject population for Prod

Question:	Answer:
1. Will you be recruiting subjects to participate in this study? If you are obtaining tissue, examining medical records, or receiving data from another institution or database (e.g., WCMC will be acting as a coordinating center receiving data from subsites), then you must answer "yes" to this question.	Yes
2. How many subjects do you intend to enroll at WCMC (Please note, subjects are considered to be enrolled in the study once they have signed the consent form. The numbers below should include those subjects who will sign the consent form but may ultimately not participate in the study due to screen failure, not meeting inclusion/exclusion criteria, etc.)	2000
3. How many subjects will be males? If male/female subjects will be enrolled regardless of gender, please indicate that here.	Male/female subjects will be enrolled regardless of gender
4. How many subjects will be females? If male/female subjects will be enrolled regardless of gender, please indicate that here.	Male/female subjects will be enrolled regardless of gender
5. What is the age range for the subjects?	Subjects of age 18 and older
6. What is the expected duration of study for individual subjects (days/months)? If this is a chart review or tissue procurement study, please indicate this here.	Chart review
7. Please indicate the types of subjects you will be enrolling:	Outpatients
8. What is the subject's state of physical health? Please indicate of seriously or terminall ill.	subjects will be enrolled regardless of physical health, ranging from healthy to terminally ill
9. Will you be targeting for enrollment of any of the following special groups: Minors, Pregnant Women/Fetuses, Neonates, Students and/or employees, Prisoners, Special racial or ethnic groups, Mentally/cognitively impaired (i.e. mentally ill, mentally retarded, emotionally disturbed, senile dementia, etc.).	No
10. Please select all of the recruitment methods for initially identifying potential subjects:	Medical records (request for HIPAA partial Waiver)
11. Please specify what Protected Health Information (PHI) will be used and disclosed without immediate authorization from subjects.	Demographic Information Other Information Medication information Other Information

12. Additional Information (if any) on Protected Health Information (PHI) used and disclosed without immediate authorization from subjects.

13. Please specify what is being reviewed (i.e. Electronic Medical Record, appointment logs, etc.)

Appointment log and electronic medical record

14. What is the plan to protect identifiers from improper use and disclosure?

Data is only recorded electronically
Data will be saved on a secure server

15. What is the plan to destroy identifiers?

At the completion of the study
Electronic identifiers will be deleted from the database

16. Additional Information (if any) on plan to protect identifiers from improper use and disclosure.

Data will be saved on redcaps database

17. With respect to the HIPAA partial waiver, will the PHI be reused or disclosed to any other person or entity? Please note, if you answer yes to this question, the study does not qualify for a HIPAA partial waiver.

No

18. Will the use or disclosure of PHI involve more than a minimal risk to privacy? If the answer to this question is Yes, then you do not qualify for a HIPAA partial waiver of Authorization. Please click on Start Over link to restart this form from the beginning.

No

19. Additional Information (if any) on plan to destroy identifiers.

N/A

20. Is it feasible to conduct the research without access to and use of PHI? If the answer to this question is Yes, then you do not qualify for a HIPAA partial waiver of Authorization. Please click on Start Over link to restart this form from the beginning.

No

21. We need to access to the PHI to check eligibility of potential subjects before we seek an authorization. Please note, if you will be requesting a waiver of HIPAA authorization in the confidentiality section, the answer to this question should be no.

No

22. Please confirm that the screening of medical records for recruitment purposes involves no more than minimal risk to potential subjects.

Yes

23. Please confirm that the screening of medical records for recruitment purpose will not adversely affect the rights and welfare of the potential subjects.

Yes

24. Please confirm that the screening of medical records for recruitment purpose could not practicably be carried out without the waiver of immediate HIPAA Authorization.

Yes

25. Please provide justification for why the screening of medical records for recruitment purpose could not practicably be carried out without the waiver of immediate HIPAA Authorization.

The Center for Gastroenterology and Hepatology sees a variety of subjects including those that are followed on a primary basis and subjects that are seen as a referral from other primary gastroenterologists and as a second

opinion. Given this nature, it would be impractical to locate subjects retrospectively for HIPAA authorization.

26. If there is more than one active trial being run by the PI or in the department/division (if known), please provide an algorithm/schema or information on how it will be determined which study the subject(s) will be offered. If none, state not applicable.

N/A

27. Will subjects receive any compensation before or after study?

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Risk Level for production

Question:	Answer:
1. What is the risk level of the proposed research study?	Minimal Risk
2. Does your study qualify for exempt review in any of the categories detailed in the More section (Please click More on the right for a list of the categories)?	No
3. Does your study qualify for expedited review in any of the categories detailed in the More section (Please click More on the right for a list of the categories)?	Yes
4. Does your study qualify for expedited review under the category: Category 1 - Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	No
5. Does your study qualify for expedited review under the category: Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	No
6. Does your study qualify for expedited review under the category: Category 3 - Prospective collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is	No

accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

7. Does your study qualify for expedited review under the category: Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

No

8. Does your study qualify for expedited review under the category: Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). PLEASE NOTE: If extra tissue is being taken during a routine clinical procedure (i.e. additional tissue that is not being taken for diagnostic purposes), you do not qualify for expedited review under this category.

Yes

9. Is this a medical record/chart/appointment log review?

Yes

10. What are the inclusive dates of the charts you will be reviewing (mm/yyyy format)?

1/1/2000-1/1/2016

11. Does your study qualify for expedited review under the category: Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

No

12. Does your study qualify for expedited review under the category: Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

No

13. This study is minimal risk but does not qualify for initial exempt or expedited review.

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Confidentiality of Data and Privacy of Subjects

Question:	Answer:
1. Will you be collecting identifiable PHI, either from the Medical Record or during the course of the study, where the data, either directly or through a code, can be linked back to an individual?	Yes
2. Are you requesting a complete HIPAA Waiver of Authorization? If you require a waiver of HIPAA authorization for some, but not all subjects, please answer no to this question and indicate in an open text field in this section which subjects you are requesting a waiver of HIPAA authorization from (e.g., you will be obtaining authorization from some subjects, but others are lost to follow-up)(Please note, the request for the HIPAA partial waiver to confirm subject eligibility is requested in the subject population section)	Yes
3. Please specify what Protected Health Information (PHI) will be used and disclosed without immediate authorization from subjects. Demographic Information, medication information, blood test results, urine test results, CT Scan results, MRI results, X-Ray results, PET Scan results, Physical Examination Information, Neurological Examination information, Psychological information, alcohol and substance use information, pathology results, HIV testing information, genetic testing results, cardiology results	demographic information, medication information, pathology results
4. Additional Information	endoscopy results, anesthesia data
5. Please specify what is being reviewed (i.e. Electronic Medical Record, appointment logs, etc.)	appointment logs to enroll subjects and electronic medical record to collect data
6. What is the plan to protect identifiers from improper use and disclosure?	Data is only recorded electronically Data will be saved on a secure server
7. Additional Information	We will be using redcaps as our secure server
8. What is the plan to destroy identifiers?	At the completion of the study Electronic identifiers will be deleted from the database
9. Additional Information	N/A
10. Will the PHI be reused or disclosed to any other person or entity?	No
11. Will the use or disclosure of PHI involve more than a minimal risk to privacy? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.	No

12. Is it feasible to conduct the research without the complete waiver of authorization? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.

13. Please explain why it is not feasible to conduct the research without the waiver.

The Center for Gastroenterology and Hepatology sees a variety of subjects including those that are followed on a primary basis and subjects that are seen as a referral from other primary gastroenterologists and as a second opinion. Given this nature, it would be impractical to locate subjects retrospectively for HIPAA authorization and informed consent.

14. Is it feasible to conduct the research without access to and use of PHI? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.

No

15. Please explain why it is not feasible to conduct the research without the access to specified PHI.

Access to PHI is required in order to collect necessary data to answer our research question, including past medical history, endoscopy data, etc.

16. Are you obtaining written HIPAA authorization from subjects by incorporating the appropriate HIPAA language into the informed consent form?

No

17. What specific safeguards will be employed to protect confidentiality of data?

Data is only recorded electronically
Data will be saved on a secure server

18. Additional Information (if any) on specific safeguards employed to protect confidentiality of data when data is recorded electronically.

We will be using redcaps as our secure server

19. Additional Information (if any) on specific safeguards employed to protect confidentiality of data when data is saved on a secure server.

We will be using redcaps as our secure server

20. Will data that identifies individual subjects be published or in any way disclosed to third parties other than project personnel or the study sponsor?

No

21. Will subjects have access to their research records while they are enrolled in the study? PLEASE NOTE: the HIPAA authorization form must include this information.

No

22. Please explain in detail the basis of your request for the temporary suspension of subjects' rights to access their research records while they are enrolled in the study. (Example: This is a double-blind study and the subjects will not have access to information about the arm of the study to which they were assigned.) PLEASE NOTE: the consent form must include this information.

Given the impracticality of locating subjects retrospectively for consent and authorization, subjects will not be informed of their enrollment in the study

23. List the specific sections of the research record or specific information subjects will not have access to while participating in the study. [Example (1): You will not have access to the information relating to the arm of the study to which you are assigned. Example (2): You will not have access to genetic test results that have no

Given the impracticality of locating subjects retrospectively for consent and authorization, subjects will not be informed of their enrollment in the study

clinical significance.] PLEASE NOTE: the consent form must include this information.

24. At what specific point in time will the suspension be lifted? [Example (1): Access to the information will be reinstated when the blinds are lifted and the primary investigator knows the arm of the study to which the subject was assigned. Example (2): When the genetic testing becomes clinically significant and subject wants to view there research records.] PLEASE NOTE: the consent form must include this information.

Given the impracticality of locating subjects retrospectively for consent and authorization, subjects will not be informed of their enrollment in the study

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Human Tissue for Prod

Question:

Answer:

1. Tissue Submission Policy: Human tissue removed during a diagnostic or therapeutic procedure must be submitted to Pathology intact and may not be incised, opened, or damaged in any way, with the exception of surgical waste (defined below). Peripheral blood is not considered tissue. Surgical waste is specifically defined by the Medical Board as: 1. Subcutaneous tissue removed to facilitate wound closure and/or 2. Tissues significantly altered or diluted by the procedure such as lens phakoemulsifications, vitrectomy specimens or liposuction specimens. Other than the surgical waste noted above, ALL tissue must go FIRST to Pathology unless an exception to the tissue submission policy is requested. 1. Is human tissue from patients at this institution (WCMC) being used in this study based on the WCMC tissue policy described above? If yes, please complete the human tissue request form, found on our website at http://weill.cornell.edu/research/forms_and_policies/irb_forms/index.html and submit to submit2pathology@med.cornell.edu. Please note, if you answer yes to this question, IRB approval will not be released until the IRB office receives confirmation of approval from Pathology. Please check "no" if this is a review of pathology reports/results only OR tissue obtained outside WCMC-NYP.

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Data and Safety Monitoring Plan for Prod

Question:

Answer:

1. Does this study qualify for exempt or initial expedited review? Yes

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Use of Drugs or Biological Agents

Question:

Answer:

1. Does this study involve the administration of an FDA regulated product, Nutritional supplement or a biological product? No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Non-Technical Research Plan Prod

Question:	Answer:
1. What is the expected end date of the study? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	12/18/2017
2. Will there be student investigators (must be older than 18 years of age)? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Yes
3. List the student names. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	1. Elen Gutmann 2. Nadir Shafiq Zaidi
4. What are their responsibilities in the project? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Data collection
5. Please list the investigator(s) who will be supervising the students. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Snell, David
6. Study Design: Include information on the hypothesis, research question, standard vs. experimental procedures (interventions happening as part of clinical care vs. those that are occurring only because the subject is part of the study), the use special or unusual equipment or procedures. Include specifics on all study interventions and their frequency and the treatment plan (For example, the dosage of a drug to be given and the frequency). For randomized studies, list the study groups and under each describe the categories of procedures. List together in a group all procedures that are part of standard of care treatment, and list together in a group all procedures that are investigative, separating and labeling the two groups. Tables and/or charts are helpful and encouraged and should be uploaded in the attachments section as a continuation of the study design. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	This will be a retrospective study. All subjects at New York Presbyterian with the diagnosis of cirrhosis who underwent EGD between the years of 2000-2016, as identified by "rule out varices" as indication for EGD will be identified via provation. We will perform a chart review to identify subjects who underwent an upper endoscopy (EGD) at NYP Cornell between 1/1/2000 and 1/1/2016. We will examine these procedure and collect information including indication for procedure, presence of food in the stomach, evidence of mechanical obstruction on EGD, other findings during endoscopy (for example, varices, portal hypertensive gastropathy, etc...) type of anesthesia used, number of endoscopies at Weill Cornell. For each subject, we will also collect clinical and laboratory information, such as FibroScan® score, liver biopsy results (modified HAI grade if available and Metavir stage of fibrosis), underlying etiology of liver disease, MELD score and childpugh class at time of endoscopy, portal pressures (if available from transjugular biopsy), age, sex, body mass index, ethnicity, comorbidities (based on Charlson comorbidity index). For each subject with cirrhosis and retained food in the stomach, we will try to reach them

with a control subject. It is not established how much delayed gastric emptying in cirrhotics actually causes consequences like impaired visualization at endoscopy. Therefore, it is meaningful to compare them to a control group. This will also allow us to determine the incidence of retained food in general with EGD, which will allow us to establish a standard incidence of retained food to compare our findings in cirrhotics. Control subjects will be selected by searching Provation to identify individuals who underwent upper endoscopies in the same time. Each control subject will be matched with a control based on age, sex, BMI and comorbidities (other than cirrhosis). Both control and cases will be excluded if the indication for procedure was dysphagia, early satiety, nausea, vomiting, abdominal bloating or GI bleeding. Indication for endoscopy in noncirrhotic patients can include: Anemia, dyspepsia, GERD, perioperative evaluation (unless surgery is for a motility or gastric outlet disorder), screening prior to anticoagulation/antiplatelet therapy, suspected celiac disease, surveillance (for PUD healing, gastric metaplasia, Barrett's, adenoma/polypoidosis syndromes, etc.)

7. Rationale and Justification for the study: for example, historical background, investigator's personal experience, pertinent medical literature. Please include any information regarding studies in animals that are pertinent to the proposed study. If this study involves an investigational drug, an FDA approved drug being used off label or that is being given according to label but for research purposes only, please indicate what are the effects of the drug for its intended use (dosage range and efficacy, data in humans plus animal studies, when appropriate. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

Up to 80% of cirrhotic patients experience abdominal bloating, pain, and belching.(1) Traditionally, it was thought that these complaints were secondary to medications (such as lactulose), organic causes such as PUD and GERD, or abdominal ascites causing increased intra-abdominal pressure. However, a growing body of literature has begun to characterize alterations in GI motility in cirrhotic patients, including gastric sensorimotor function, gastric emptying, and small bowel transit.(2) Recent data have demonstrated that impaired gastrointestinal (GI) motility is common in cirrhotic patients. Observed abnormalities in cirrhosis include altered gastric sensorimotor function, delayed gastric emptying, and decreased small bowel motility[ABJ1] . Gastric emptying in particular is severely prolonged in cirrhotic subjects, and this finding likely accounts for the GI symptoms of bloating and early satiety commonly reported by this population.(3) Cirrhotic subjects routinely undergo upper endoscopy as screening for esophageal and gastric varices for primary prevention of variceal hemorrhage, a significant cause of morbidity/mortality in this population. Preparation for upper endoscopy involves the subject abstaining from food intake for 8 hours prior to the procedure to ensure an empty stomach. The diagnostic yield of an upper endoscopy, in terms of identifying varices and other mucosal changes associated with portal hypertension in cirrhosis, depends on the ability of the endoscopist to completely visualize the stomach. Retained food at

the time of endoscopy can significantly impair this yield. In addition, having food present in the stomach increases the risk for procedure-related complications such as scope-induced trauma or perforation, or aspiration of gastric contents during anesthesia. As cirrhotic subjects are at risk for delayed gastric emptying and routinely require upper endoscopy, they might be at increased risk of retained gastric contents at endoscopy compared to noncirrhotic subjects. The aim of this study is to retrospectively identify the incidence of retained food at the time of endoscopy in age-matched cirrhotic vs. noncirrhotic subjects. We will also identify the miss rate for endoscopic findings and the procedure complication rate when retained food is present in cirrhotic subjects. 1. Fritz E, Hammer J. Gastrointestinal symptoms in patients with liver cirrhosis are linked to impaired quality of life and psychological distress. *Eur J Gastroenterol Hepatol* 2009; 21:460-465. 2. Kalaitzakis E. Gastrointestinal dysfunction in liver cirrhosis. *World J Gastroenterol* 2014 Oct 28; 20(40): 14686-14695. 3. Isobe H, Sakai H, Sato M, Sakamoto S, Nawata H. Delayed gastric emptying in patients with liver cirrhosis. *Digestive Diseases and Sciences*. 1994 May;39(5):983-7.

8. Primary Objective: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

1. To identify the incidence of food in the stomach during upper endoscopy in cirrhotic subjects as compared with subjects without cirrhosis 2. To determine the miss rate (defined as a pertinent finding on a subsequent EGD within one year not found on index EGD when food was retained) for endoscopic findings in those cirrhotic subjects who have retained food at the time of upper endoscopy and compare this to the accepted standard. 3. To determine the procedure complication rate in cirrhotic subjects with retained food at the time of upper endoscopy.

9. Secondary Objective: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

1. To evaluate the risk factors for retained food at the time of endoscopy within the cirrhotic subject cohort

10. Statistical Considerations (e.g. justification for sample size or "n". Please include the total number of subjects to be recruited at WCMC, the total number of subjects at all site (if a multisite study), expected total screening failures/dropouts at WCMC (if applicable), How the data will be analyzed, etc: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

This is a retrospective cohort study of cirrhotic subjects who had an upper endoscopy for screening for esophageal varices. All subjects who meeting inclusion/exclusion criteria will be included for statistical evaluation. Baseline characteristics will be compared between the groups by Fisher's exact test for categorical variables and two tailed t-test for all continuous variables. A p-value of < 0.05 will be considered statistically significant. Univariate and multivariate analysis will be performed to identify possible predictors of food present in the stomach during endoscopy. All statistical analysis will be performed with SAS 9.4. Based on an

11. Inclusion Criteria: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

12. Exclusion Criteria: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

13. Will you be collecting as a part of this research study any of the following: tissue from surgical pathology, blood, urine, bone marrow aspirate or other biological samples?

14. Does the research planned in this project involve any form of invasive procedure (minimally invasive or greater, including venipuncture)?

15. Does the research planned in this project involve any major changes in diet or exercise?

16. Does the research planned in this project involve any administration of physical stimuli other than auditory and visual stimuli associated with normal classroom situations?

17. Does the research planned in this project involve any deprivation of physiological requirements such as nutrition or sleep, manipulation of psychological and/or social variables (i.e. sensory deprivation, social isolation, psychological stress, etc.?)

18. Does the research planned in this project involve any use of deceptive techniques without the knowledge of the subject?

expected rate of gastroparesis in ~5% of patients in the general population (I looked this up quickly on pubmed, but there might be other studies that disagree), and based on Dr. Jesudian's estimation of 15% of patients with retained food in our cirrhotic cohort, we would need ~133 patients in each group to have 80% power to detect a difference between the two groups. Assuming that 35% of patients will fall into an exclusion category (I did not base the 35% number on any data, it just seemed like a conservative number), we will need to look through approximately 431 charts (205 in each group), to achieve the correct number of patients to allow our study to have the appropriate power.

1. Men or women at least 18 years of age
2. Subjects who have undergone an upper endoscopy at our institution.

1. Age less than 18 years
2. The following indications for upper endoscopy will be excluded: food impaction, foreign body, hematemesis, melena, hematochezia, abdominal pain, nausea/vomiting, bloating, early satiety, weight loss.
3. Subjects with known GI motility disorders such as gastroparesis, or taking medications with decreased intestinal transit time as a side effect such as opiates.
4. Subjects with diabetes and alcoholic liver disease will be analyzed as a separate cohort given their known association with delayed intestinal motility

No

No

No

No

No

No

Yes

19. Does the research planned in this project involve any probing of information which might be considered personal or sensitive, including the examination of the medical record?

20. Please explain in detail.

This study is a retrospective chart review and thus will involve the review of medical record, including basic demographic information, past medical history, endoscopy results and disease severity index.

21. Does the research planned in this project involve any presentation to the subject of any materials which they might find to be offensive, threatening or degrading?

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Radiation Safety for Prod

Question:

Answer:

1. Will this study involve in vivo imaging or image guided interventions (e.g., CT, US, MRI, x-ray, fluoroscopy, etc.)?

No

2. Will this study involve the use of radioisotopes or other sources of ionizing radiation (i.e., diagnostic and/or therapeutic radiation, e.g. xray machines, CT, cardiac catheterization, radioisotopes, radiation therapy, etc.) for purposes other than standard of care either entirely or in part? (i.e., subjects would not be having these procedures in the manner described in the protocol and informed consent if they were not enrolled in the study; or subjects might have some of these procedures for standard of care and some of these procedures outside of normal standard of care)? If so, please obtain review and approval from the Radiation Safety Committee and attach the approval documentation to the eIRB application prior to submission. You must receive approval from the Radiation Safety Committee (RSC) before IRB approval can be released. Contact the RSC Chair, Stanley Goldsmith, M.D. at 212-746-4588 or sjg2002@med.cornell.edu for more information. Please contact Peter Capitelli (pec2008@med.cornell.edu) the Radiation Safety Officer, for assistance in calculating the dosimetry prior to submitting the protocol to the IRB or Radiology for review.

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Test Articles and Bioavailability/Bioequivalence S

Question:

Answer:

1. Will this study involve the use of test articles and/or is a bioavailability/bioequivalence study? No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Additional Information for prod

Question:

Answer:

1. Will this study take place in WCMC/NYP? Yes
2. Please provide information on where in WCMC/NYP this study will take place (i.e., WCMC or NYP specific clinics or laboratory space or CBIC, etc.) This study is a chart review
3. Will this study take place in a private office or another location outside of WCMC/NYP? No
4. Please indicate the number of externally funded research and/or sponsored projects that this IRB protocol falls under. If this protocol is funded internally please enter 0. Externally funded research and/or sponsored projects include the following. Please click "More" for definitions of these terms. A) Grant/Contract/Subaward/Clinical Trial Grant B) Clinical Trial Agreement (Investigator Initiated) C) Clinical Trial Agreement (Industry Initiated) D) Sponsored Research Agreement (Investigator Initiated) E) Sponsored Research Agreement (Industry Initiated) F) Material Transfer Agreement (Recipient Initiated) G) Material Transfer Agreement (Provider Initiated) H) Other (i.e. Data Use Agreement, Registry) 0

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Potential Benefits for Prod

Question:

1. Please assess potential benefits to subjects and to society which may accrue as a result of this research, analyzing the risk/benefit ratio and why the risks are justified by the potential benefits.

Answer:

Up to 80% of cirrhotic subjects experience abdominal bloating, pain, and belching. Traditionally, it was thought that these complaints were secondary to medications (such as lactulose), organic causes such as PUD and GERD, or abdominal ascites causing increased intra-abdominal pressure. However, a growing body of literature has begun to characterize alterations in GI motility in cirrhotic subjects, including gastric sensorimotor function, gastric emptying, and small bowel transit. Due to the individual and societal burden conferred by GI dysmotility in the cirrhotic population, there is considerable value in studying approaches to improve GI function and symptoms in these subjects. Assessment of the incidence of food in the stomach will be the first step in understanding the burden of delayed gastric motility in cirrhotics. This will also give us a better understanding of the risk factors associated with delayed gastric motility in cirrhotic subjects, which will direct clinicians in treatment, and benefit anesthesiologists in assessing risk for aspiration during endoscopy. In addition, by determining the miss rate of gastric varices, portal gastropathy and other non-cirrhotic findings in those who have retained food on initial endoscopy, this study will provide clinicians with valuable insight regarding need for re-screening. This is the only study to our knowledge that will review risk factors associated with retained food on endoscopy in cirrhotic subjects. It will thereby allow for further understanding of the pathophysiology of delayed intestinal transit in subjects with cirrhosis, which can guide treatment options. Furthermore, by understanding missed-detection rates in these subjects, this study will guide clinicians on the need for further diagnostic procedures. Currently, there is no effective treatment to improve gastrointestinal dysmotility and its associated symptoms for subjects with cirrhosis short of LT. If our data provides valuable information regarding this issue, there will be strong justification to conduct further trials aimed at studying GI disturbance in cirrhotic subjects and ultimately improving outcomes for these subjects.

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Institutional Biosafety Committee for Prod

Question:

Answer:

1. Will human research subjects be exposed to the deliberate transfer of either recombinant nucleic acid molecules, DNA or RNA derived from recombinant nucleic acid molecules, or synthetic nucleic acid molecules (Human Gene Transfer)?

No

2. Does this study involve the use of non-FDA approved biological agents in human subjects, i.e., use of a biological agent that has the ability to replicate or potentially cause disease in humans (virus, bacteria, vaccine or etiological agent)?

No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Clinical Translational Science Center for Prod

Question:	Answer:
1. Will the clinical Translational Science Center be used? (This would include the use of the RedCap data base program)	Yes
2. Will the pediatric unit be used?	No
3. Will the adult unit be used?	No
4. In what capacity will the CTSC be used? Please explain	We will be using Redcaps

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Amendment Questionnaire for Prod

Question:

Answer:

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Informed Consent for Prod

Question:

Answer:

1. Are you requesting a waiver of informed consent, either written or oral? If you require a waiver of informed consent for some, but not all subjects, please answer no to this question and indicate in the open text field which subjects you are requesting a waiver of informed consent from (e.g., you will be obtaining consent from some subjects, but others are lost to follow-up).

Yes

2. Does your research fall under the following two categories: 1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. AND 2) The research could not practicably be carried out without the waiver.

No

3. Does your research fall under the following four categories: 1) The research involves no more than minimal risk to subjects; AND 2) The waiver/alteration will not adversely affect the rights and welfare of the subjects; AND 3) The research could not practicably be carried out without the waiver; AND 4) Whenever appropriate, the subjects will be provided with additional pertinent information.

Yes

4. The research involves no more than minimal risk to subjects.

Yes

5. The waiver/alteration will not adversely affect the rights and welfare of the subjects.

Yes

6. Please justify why the waiver/alteration will not adversely affect the rights and welfare of the subjects.

De-identified information will be collected and data will be stored electronically in a secure server (Redcaps) and destroyed upon completion of the study. PHI will not be shared with any outside parties.

7. The research could not practicably be carried out without the waiver.

Yes

8. Please justify why the research could not practicably be carried out without the waiver.

The Center for Gastroenterology and Hepatology sees a variety of subjects including those that are followed on a primary basis and subjects that are seen as a referral from other primary gastroenterologists and as a second opinion. Given this nature, it would be impractical to locate subjects retrospectively for HIPAA authorization.

9. Whenever appropriate, the subjects will be provided with additional pertinent information. Yes

10. Will you be using the standard hospital consent form? No

Additional Form/s

Protocol Number: 1512016797A002 **Title:** A retrospective review of gastric emptying in cirrhotic subjects. **Principal Investigator:** Jesudian, Arun B.

Questionnaire Name: Medical Devices Questionnaire

Question:

Answer:

1. Will any medical devices as defined by FDA regulations be used in this protocol? No