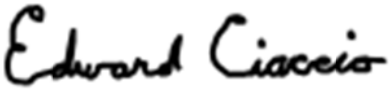
31908-INSTITUTIONAL REVIEW BOARD STATEMENT

Name of Journal: *World Journal of Gastrointestinal Endoscopy*
Manuscript NO: 31908
Manuscript Type: Original Article
Retrospective Study

Use of shape-from-shading to characterize mucosal topography in celiac disease videocapsule images

Edward J Ciaccio, Govind Bhagat, Suzanne K Lewis, Peter H Green

Institutional review board statement: The study protocol has been approved by the Columbia University Medical Center IRB.



Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol:	AAAF3919(M00Y06)	**Protocol Status:**	Approved
Effective Date:	03/03/2017	**Expiration Date:**	03/02/2018
Originating Department Code:		MED General Medicine (751880X)	
Principal Investigator:		Green, Peter H (pg11)	
From what Columbia campus does this research originate:		Medical Center	
Title:	Video Capsule Endoscopy in Celiac Disease		
Protocol Version #:		**Abbreviated Title:**	Capsule Endoscopy in Celiac Disease
Was this protocol previously assigned a number by an IRB:			Yes
Previous Columbia IRB#:	AAAF3919	**Previous External IRB#:**	

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?

No

IRB Expedited Determination

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 diagnoses).

Renewal Information

Enrollment status:

Open to enrollment or ongoing review of records/specimens

Provide any additional information necessary to explain the study status:

We apologize for the lapse in protocol; more than one individual was working on the protocol previously. From now on Ms. Maria Teresa Minaya, the clinical coordinator, will be responsible and ensure that the protocol is up-to-date. No additional subjects were enrolled during the lapse interval - we corrected this typographical error in the subject section. No charts were reviewed nor additional data analyses were done during the lapse interval. If re-approved, as more patient data is analyzed, we expect that the significance of the results will increase based on the power test, which will make for a more efficacious study.

Since the last renewal:

Have there been any changes in the relevant literature that would affect the study design or procedures?

No

Have there been any interim findings associated with this study?

Yes

Please Describe:

We have found that the level of resolution of video capsule endoscopy is sometimes sufficient to detect villous atrophy. This is important because previously it was thought this could only be done by taking tissue biopsies which are analyzed under light microscopy.

Have there been any publications resulting from this study?

Yes

Please Describe:

Quantitative image analysis of celiac disease.
Ciaccio EJ, Bhagat G, Lewis SK, Green PH.
World J Gastroenterol. 2015 Mar 7;21(9):2577-81. doi: 10.3748/wjg.v21.i9.2577.

Use of basis images for detection and classification of celiac disease.
Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, Green PH.
Biomed Mater Eng. 2014;24(6):1913-23. doi: 10.3233/BME-141000.

Have any participants been enrolled using the Short Form process?

No

Is there a Data Monitoring Committee (DMC), Data Safety Monitoring Board (DSMB), or other monitoring entity for this study?

No

Is an annual Progress Report required by the funding organization or coordinating center for this study?

No

Does this submission include a modification?

No

Has the consent form been revised in this submission?

No

Does this submission include a report of a protocol violation?

No

Attributes

Special review type: Check all that apply or check "None of the Above" box.

[ ]Review for 45 CFR 46.118 Determination (involvement of human subjects is anticipated but is not yet defined)
[ ]Funding review for Administrative IRB approval (such as for Center or Training Grants)
[x]None of the above

IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?

I don't know

Is this research part of a multicenter study?

No

Please indicate if any of the following University resources are utilized:

[ ] Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)
[ ] CTSA-Irving Institute Clinical Research Resource (CRR)
[ ] CTSA- Irving Institute Columbia Community Partnership for Health (CCPH)
[x] None of the above

Background

Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives.

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Study Purpose and Rationale:

Provide pertinent background description with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

The use of videocapsule endoscopy is helpful to assist with the diagnosis and treatment of celiac disease. Because standard endoscopy is invasive, it cannot be used to characterize all patients, and is also expensive and time consuming. The videocapsule method is mostly noninvasive. It provides images, currently 2 frames per second, with a resolution of 576 x 576 pixels per image, which works out to approximately 1-2 millimeters. Using these sequential images as a videoclip, the gastroenterologist can determine areas of abnormality in suspected celiac patients as well as efficacy or treatment on a gluten-free diet for know celiac patients. Where there is pathology, this is caused by villous atrophy in the small intestinal mucosa. Untreated, this can lead to damage to the small intestine and to other parts of the body.

References

Select item 25226887

Use of basis images for detection and classification of celiac disease.

Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.

Biomed Mater Eng. 2014;24(6):1913-23. doi: 10.3233/BME-141000.

Implementation of a polling protocol for predicting celiac disease in videocapsule analysis.

Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.

World J Gastrointest Endosc. 2013 Jul 16;5(7):313-22. doi: 10.4253/wjge.v5.i7.313.

Study Design:

Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

We are developing an imaging analysis system to detect areas of pathology in the small intestinal mucosa of celiac disease patients. This pathology tends to be patchy, and may be minimally evident in videocapsule image series. Sometimes, no pathology can be detected by visual inspection. However, by using computer automated techniques and quantitative analyses, it is possible to detect and even to assign a numerical score to areas of pathology. This is an improvement to older techniques that require the clinician to assign a qualitative score. Scoring using the older method can be biased and may not be very accurate. Knowing where pathology is and the degree of pathology is essential to diagnosis and treatment of the patient.

References

Methods to quantitate videocapsule endoscopy images in celiac disease.
Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.
Biomed Mater Eng. 2014;24(6):1895-911. doi: 10.3233/BME-140999. Review.

Implementation of a polling protocol for predicting celiac disease in videocapsule analysis.
Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.
World J Gastrointest Endosc. 2013 Jul 16;5(7):313-22. doi: 10.4253/wjge.v5.i7.313.

Use of shape-from-shading to estimate three-dimensional architecture in the small intestinal lumen of celiac and control patients.
Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.
Comput Methods Programs Biomed. 2013 Sep;111(3):676-84. doi: 10.1016/j.cmpb.2013.06.002. Epub 2013 Jun 29.

Select item 23674375
Celiac disease in patients with type 1 diabetes: screening and diagnostic practices.
Simpson SM, **Ciaccio EJ**, Case S, Jaffe N, Mahadov S, Lebwohl B, **Green** PH.
Diabetes Educ. 2013 Jul-Aug;39(4):532-40. doi: 10.1177/0145721713487998. Epub 2013 May 14.

Statistical Procedures:

Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Using a power test with alpha level of 0.05, the necessary N for statistical significance between groups (villous atrophy versus not) is on the order of N = 100 for each population. To obtain this value requires the enrollment of patients over several years. Many newly diagnosed celiac patients need to be excluded from the study due to presence of comorbidity due to presence of preexisting conditions.

References

Detection of villous atrophy using endoscopic images for the diagnosis of celiac disease.

Ciaccio EJ, Lewis SK, **Green** PH.

Dig Dis Sci. 2013 May;58(5):1167-9. doi: 10.1007/s10620-013-2618-9. No abstract available.

Select item 22644741

Quantitative estimates of motility from videocapsule endoscopy are useful to discern celiac patients from controls.

Ciaccio EJ, Tennyson CA, Bhagat G, Lewis SK, **Green** PH.

Dig Dis Sci. 2012 Nov;57(11):2936-43. doi: 10.1007/s10620-012-2225-1. Epub 2012 May 30.

P

Exempt and Expedited

Is the purpose of this submission to obtain an exemption determination, in accordance with 45CFR46.101(b):
No

Is the purpose of this submission to seek expedited review , as per the federal categories referenced in 45CFR46.110?
Yes

Is the risk of harm to which subjects will be exposed as a result of this research no more than minimal?
Yes

Select the category or categories of research into which study procedures fall.

[ ] 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.

[ ] 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.

PLEASE NOTE: If blood is collected through an existing catheter, you do not qualify for expedited review under this 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 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.
[ ] 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.
[ ] 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.
[x] Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.
[ ] 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Do all procedures fall into one or more of the categories listed above?

Y

NOTE: This project appears to be eligible for expedited review.

Funding

Is there any external funding or support that is applied for or awarded, or are you the recipient of a gift, for this project?

No

Locations

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Columbia/CUMC	180 Fort washington ave Suite 936				

Personnel

UNI	Name	Role	Department	Edit/View	Obtaining Informed Consent
pg11	Green, Peter H	Principal Investigator	MED Digestive & Liver Diseases (751870X)	Edit	N
bl114	Lebwohl, Benjamin	Investigator	MED Digestive & Liver Diseases (751870X)	Edit	N
ejc6	Ciaccio, Edward	Investigator	MED Cardiology (751830X)	Edit	N
gb96	Bhagat, Govind	Investigator	PAT Pathology (753800X)	Edit	N
mtm2111	Minaya, Maria	Investigator	MED Clinical Md Practice (751840X)	Edit	N
skl3	Lewis, Suzanne	Investigator	MED Clinical Md Practice (751840X)	Edit	N

Training and COI

The PI must ensure that each individual that is added as personnel has met the training requirements for this study (http://www.cumc.columbia.edu/dept/irb/education/index.html). For help identifying which research compliance trainings you may be required to take, visit the Research Compliance Training Finder.

UNI	Name	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	S-I	CRC	Good Clinical Practice (GCP)	GCP - Third-party tracking	Genetic Research Consent
pg11	Green, Peter H	12/04/2016	07/16/2004	07/08/2016	03/15/2014	07/08/2016					
bl114	Lebwohl, Benjamin	02/05/2017	10/31/2013	09/13/2016	09/13/2016	09/13/2016					
ejc6	Ciaccio, Edward	02/13/2017	02/23/2008	12/18/2016	06/15/2010	12/18/2016					
gb96	Bhagat, Govind	02/17/2017	04/21/2004	04/27/2015	04/27/2015	04/27/2015					
mtm2111	Minaya, Maria	11/18/2016	01/14/2005	03/23/2015	03/23/2015	03/23/2015		12/22/2010			
skl3	Lewis, Suzanne	10/13/2016	02/27/2009	10/23/2016	10/23/2016	10/23/2016					

Departmental Approvers

Electronic Signature: Peter H Green (751870X) - Principal Investigator Date: 03/02/2017

Electronic Signature: Govind Bhagat (753800X) - Investigator Date: 02/13/2017

Electronic Signature: Maria Minaya (751840X) - Investigator Date: 02/13/2017

Electronic Signature: Edward Ciaccio (751830X) - Investigator Date: 02/13/2017

Electronic Signature: Suzanne Lewis (751840X) - Investigator Date: 02/13/2017

Privacy & Data Security

Indicate the methods by which data/research records will be maintained or stored (select all that apply):

[ ]Hardcopy (i.e., paper)

[x]Electronic

Where will the data be stored?

Y

[x]On a System

[ ]On an Endpoint

Does this study involve the receipt or collection of Sensitive Data?

No

Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage elements identified above (e.g. hard copy, electronic, system, and/or endpoint):

The data will only be acquired and stored in electronic form. The data is acquired at the videocapsule imaging console computer by authorized gastroenterologists. This is done as the normal course of diagnosis and treatment of suspected and known celiac disease patients. The data is archived on a secure approved computer and storage system. Patient identifiers are removed prior to quantitative analysis. Once patient identifiers are removed, the data (video clips) are transferred for quantitative analysis.

Is there or will there be a Certificate of Confidentiality (CoC) for this research?

No

Provide a description of the protections in place to safeguard participants' privacy while information is being collected:

When the archived files are stored as distinct videoclips, the patient names are automatically removed from the files. They can then be used for quantitative analysis.

Procedures

Is this project a clinical trial?

No

Is this project associated with, or an extension of, an existing Rascal protocol?

No

Do study procedures involve any of the following?

Analysis of existing data and/or prospective record review

Yes

Audio and/or video recording of research subjects

No

Behavioral Intervention?

No

Biological specimens (collection or use of)

No

Cancer-related research

No

Drugs or Biologics

No

Future use of data and/or specimens

No

Genetic research

No

Human embryos or human embryonic stem cells

No

Imaging procedures or radiation

No

Medical Devices

No

Surgical procedures that would not otherwise be conducted or are beyond standard of care

No

Will any of the following qualitative research methods be used?

Survey/interview/questionnaire

No

Systematic observation of public or group behavior

No

Program evaluation

No

Will any of the following tests or evaluations be used?

Cognitive testing

No

Educational testing

No

Non-invasive physical measurements

No

Taste testing

No

Is there an external protocol that describes ALL procedures in this study?

No

Please describe ALL study procedures in detail.

NOTE: Be sure to detail all of the procedures above to which a "yes" response was selected. Also detail any additional procedures that may or may not fall into the categories listed above.

Once patient data has been archived, it will be sent for analysis without patient identifiers. The image series is preprocessed by transferring to grayscale format. Algorithms are then used to analyse the data. The algorithms estimate the degree of villous atrophy in the images, if any. The algorithms are used to analyze images obtained at the level of the small intestine. The results are tabulated by patient number, assigned to each patient.

Analysis of Existing Data and/or Prospective Record Review

Indicate whether the data that will be collected or utilized for the proposed study are in existence as of the current IRB submission date.

All of the data are in existence

Provide the date range of the existing data, documents, or records (e.g., medical charts, school records, census data)

Beginning Date: 11/15/2010
End Date: 09/15/2015

Note that end dates beyond the initial IRB Protocol submission date or future requests for a date parameter extension beyond the provided end date may require informed consent and HIPAA Authorization to be obtained from subjects.

Data will be obtained from (select all that apply):

[x] Columbia and/or NYP (e.g., departmental databases/systems, patient charts, Eclipsys, WebCIS, administrative/billing records, etc.)

Select all that apply:

[x] Data to be analyzed were or will be collected for clinical care

[ ] Data to be analyzed were or will be collected for nonresearch purposes other than for clinical care (e.g., student records, class evaluation, administrative records, etc.,)

[ ] Data originate from an IRB approved protocol

[ ] Other

[ ] Outside Columbia and/or NYP:

Will a member of the research team be abstracting data directly from source documents?

No

If any existing data was obtained from a prior research study, was any member of the current research team involved (e.g., obtained consent, performed study procedures, conducted data analysis) in the project or

procedures that collected and/or used identifiable information?

N/A

Indicate the manner in which the existing data and/or the records to be reviewed prospectively will be collected or received:
(Select all that apply. At least one must be selected.)

[ ] Contains direct identifiers (e.g., name, MRN, date of birth)
[ ] Coded and the research team has the key and can link the data to direct identifiers
[ ] Coded and the research team does not have access to the key to link data to direct identifiers
[ ] Prior to the receipt of the data by the research team submitting this protocol, the identifiers will be removed and no link will remain.
[x] The information was originally or will be collected without identifiers

If data are collected or received at any point in time with direct identifiers or linked to identifiers, then the data are considered to be identifiable, and the requirements for Informed Consent (or a waiver, if applicable) and HIPAA Authorization (or a waiver, if applicable) apply. The necessary information will need to be included in the respective sections of the submission.

Recruitment And Consent

Recruitment:

Describe how participants will be recruited:
Patients are not recruited. Analysis of retrospective data only.

Select all methods by which participants will be recruited:

[x] Study does not involve recruitment procedures
[ ] Person to Person
[ ] Radio
[ ] Newspapers
[ ] Direct Mail
[ ] Website
[ ] Email
[ ] Television
[ ] Telephone
[ ] Flyer/Handout
[ ] Newsletter/Magazine/Journal
[ ] ResearchMatch
[ ] CUMC RecruitMe

Informed Consent Process:

Informed Consent Process, Waiver or Exemption: Select all that apply

[ ] Informed consent with written documentation will be obtained from the research participant or appropriate representative.

[ ] Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.

[ ] A waiver of some or all elements of informed consent (45 CFR 46.116) is requested.

[ ] Planned Emergency Research with an exception from informed consent as per 21 CFR 50.24.

[x] Informed consent is not required; this is exempt research.

Although informed consent is not required for exempt research, when there will be interaction with potential subjects for the purpose of the project, it is recommended that there be a process to provide information about the research (e.g., the elements of informed consent could be provided in an information sheet or consent script) and allow subjects the opportunity to confirm their agreement to participate.

Describe how participants will be informed about the research, if applicable:
The data acquired is retrospective.

Subject Language

Language of subjects is unknown/irrelevant (e.g., record reviews, mass mailing of surveys)

Capacity to Provide Consent:

Do you anticipate using surrogate consent or is research being done in a population where capacity to consent may be questionable?
No

Research Aims & Abstracts

Research Question(s)/Hypothesis(es):

1. Can video capsule endoscopy provide a reliable way to predict villous atrophy when compared to the gold standard
of histology?

2. Do video capsule endoscopy studies of celiac patients have any gastrointestinal transit differences when compared to
control patients?

3. Can a computerized system be used to accurately predict villous atrophy in images of video

capsule endoscopy
studies?

Scientific Abstract:

Celiac disease is a common autoimmune disease, occurring in about 1% of the population worldwide, and is diagnosed via endoscopic biopsy of the small intestine. Endoscopy is an invasive procedure usually requiring sedation. Videocapsule endoscopy can potentially be used to examine the entire small bowel in a less invasive manner for both diagnostic and monitoring purposes. In patients with symptoms, capsule endoscopy can examine distant pathology. Visual scoring of videocapsule images is a subjective process that depends on the expertise of the capsule reader. We will conduct a retrospective quantitative analysis of patients with videocapsule endoscopy studies. We hope to examine the significant findings of these studies as compared to patients without celiac disease. We also hope to develop a quantitative method for scoring villous atrophy based on capsule endoscopy images.

Lay Abstract:

Celiac disease is a common autoimmune disease triggered by the ingestion of gluten, a protein found in grains such as wheat, rye, and barley. Celiac disease causes damage to the small intestine. Celiac disease is diagnosed by examining pieces of tisse obtained from the small intestine during a procedure called endoscopy. In an endoscopy, a patient is given medications for sedation and a small tube with a camera and light is passed into the mouth and eventually small intestine. Video capsule endoscopy is a procedure that is performed when a patient swallows a pill that contains a camera. The pill camera takes pictures of the small intestine as it travels naturally through the gastrointestinal tract. The research study will review previous studies of patients with and without celiac disease. The study will quantitatively examine the abnormalities seen in patients with celiac disease using image processing techniques. The study will attempt to develop a video capsule endoscopy scoring system to predict intestinal damage as compared to biopsies of the intestine.

Risks, Benefits & Monitoring

Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives. .

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

Potential Risks:

Provide information regarding all risks to participants that are directly related to participation in this protocol, including any potential for a breach of confidentiality. Risks associated with any of the items described in the

Procedures section of this submission should be outlined here if they are not captured in a stand-alone protocol. Risks of procedures that individuals would be exposed to regardless of whether they choose to participate in this research need not be detailed in this section, unless evaluation of those risks is the focus of this research. When applicable, the likelihood of certain risks should be explained and data on risks that have been encountered in past studies should be provided.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

There are no potential risks, as the data is acquire from a retrospective database.

Potential Benefits:

Provide information regarding any anticipated benefits of participating in this research. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit to participants/subjects, describe benefits to society. Please note that elements of participation such as compensation, access to medical care, receiving study results, etc. are not considered benefits of research participation.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

The benefits are improvement in the diagnosis and treatment of celiac disease. By using videocapsule endoscopy, the analysis is basically noninvasive as compared with standard endoscopic procedures. The videocapsule endoscopy procedure is also less costly and less time consuming as compared with standard endoscopy.

Alternatives:

If this research involves an intervention that presents greater than minimal risk to participants, describe available alternative interventions and provide data to support their efficacy and/or availability. Note, participants always have the option not to participate in research.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

There are no interventions to the patients. All patient data is retrospective.

Data and Safety Monitoring:

Describe how data and safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites as well.

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Data is retrospective and therefore patients are not monitored. Data confidentiality is monitored by ensuring that the computerized system is up-to-date. The computerized system is a Medtronic Given Imaging product, and all updates needed by the system as required by Medtronic Given Imaging are done.

Subjects

Unless otherwise noted, the information entered in this section should reflect the number of subjects enrolled or accrued under the purview of Columbia researchers, whether at Columbia or elsewhere.

Target enrollment:

100

Number enrolled to date:

67

Number enrolled since the last renewal or, if this is the first renewal, since the initial approval:

0

Number anticipated to be enrolled in the next approval period:

10

Does this study involve screening/assessment procedures to determine subject eligibility?

No

Of the number of subjects enrolled, or the number accrued for interventional studies with a screening process:

How many remain on the study?

43

How many are off study?

24

How many completed the study?

24

Have any withdrawn of their own initiative?

No

Have any been removed by PI?

No

Have any been lost to follow-up?

No

Have any died while on study?

No

Have any subject complaints been received?

No

Is this a multi-center study?

No

Does this study have one or more components that apply to a subset of the overall study population (e.g. Phase 1/2, sub-studies)?

No

Of the number enrolled, or the number accrued for interventional studies with a screening process, indicate:

Population Gender

Females	Males	Non Specific
66%	33%	1%

Population Age

0-7	8-17	18-65	>65	Non Specific
0%	0%	80%	20%	0%

Population Race

American Indian/Alaskan Native	Asian	Native Hawaiian or Other Pacific Islander	Black or African American	White	More than One Race	Non-Specific
10%	10%	10%	10%	40%	10%	10%

Population Ethnicity

Hispanic or Latino	Not Hispanic or Latino	Non-Specific
20%	70%	10%

Vulnerable Populations as per 45 CFR 46:

Will children/minors be enrolled

No

Will pregnant women/fetuses/neonates be targeted for enrollment?

No

Will prisoners be targeted for enrollment?

No

Other Vulnerable Populations:

[ ]Individuals lacking capacity to provide consent

[ ]CU/NYPH Employees/Residents/Fellows/Interns/Students

[ ]Economically disadvantaged

[ ]Educationally disadvantaged

[ ]Non-English speaking

[ ]Other Vulnerable populations

[x]None of the Populations listed above will be targeted for Enrollment

Subject Population Justification:

Celiac disease is evident in patients of all races and ethnicities; therefore a broad consensus of population is needed for quantitative analysis.

Does this study involve compensation or reimbursement to subjects?

No

Attached HIPAA Forms

Number	Type	Title	Status
AAAC8893	B	Capsule endoscopy in celiac patients	Approve

Documents

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	Corrective action plan AAAF3919	Other	Corrective action plan AAAF3919.pdf	Y		02/28/2017	Maria Minaya (mtm2111)