

1.0 General Information

1.1 *Please enter the full title of your study:

Comparing outcomes, efficiency and cost effectiveness of pediatric endoscopic procedures at tertiary care centers vs satellite centers

1.2 *Please enter 3 keywords or Short Study Title to describe the study:

Endoscopy, Pediatric GI, outcomes

2.0 Add Department(s)

2.1 List of Departments associated with this study:

Primary Dept?

Department Name

- UH - Pediatrics
- UH - Pediatric Gastroenterology and Nutrition

3.0 Assign key project personnel(KSP) access to the project

***The current project status does not allow for changes to the Key Study Personnel. If you wish to change the Key Study Personnel, please contact the IRB.**

3.1 *Please add a Principal Investigator for the project:

Erin Crawford

Select if applicable

Student

Resident

Fellow

Department Chair

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

- Ali Khalili
Co-Principal Investigator

Co-Principal Investigator		
B) Research Support Staff		
3.3 *Please add a Project Contact:		
01. Ali Khalili		
<hr/> <p>The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).</p>		
3.4 If applicable, please add a Faculty Advisor:		
Thomas J. Sferra		
3.5 If applicable, please select the Designated Department Approval(s):		
01. Rebecca A Hazen		
Department Signoff Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).		

4.0 Which Board?

4.1 Select Human Subject Research to begin the application process.

ATTENTION: The CWRU IACUC will no longer accept any type of submission in the School of Medicine's iRIS system as of Monday, August 1, 2016.

<https://cortex.case.edu>

You may still log into iRIS to view any and all protocols you're listed on, but in a **Read Only role.**

Effective Monday, August 1, 2016 the IACUC will only accept protocol submissions within the eSirius3G system <http://cwru.ntmcs.com/esirius3g/>

- Human Subjects Research

Effective December 1, 2013 all new applications (Cancer and Non Cancer) must use the new template.

Cancer studies that were previously approved on the Cancer template may use the old template

- Old Case Cancer IRB forms (NO NEW Submissions).
- Every other study type (New, Amendment, Continuing Review, paper Registration)

5.0

Department Division

5.1 Please select a department from the list.
Then, if applicable, select a department division

:	Pediatrics
:	Pediatric Gastroenterology

6.0

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD FOR HUMAN INVESTIGATION

PROTOCOL APPLICATION

6.1 Are you requesting determination as to whether your project is Non-Human Subject Research (NHR)? i.e. case reports, quality improvement (QI) projects, etc.

Yes • No

6.2 Are you requesting determination as to whether your project qualifies for exemption as described in 45 CFR 46 / 21 CFR 56.104?

Yes • No

6.3 Are you notifying the IRB of emergency use of a test article allowed under FDA regulations 21 CFR 312.36?

Yes • No

7.0

New Study or Registration of Paper-Based Study

7.1 This submission is...1) **New Study**: a new study/project

2) **Registration**: a paper-based study that has been previously submitted and is currently approved by the UHCMC IRB that you are registering in iRIS or

3) **Already in iRIS**: a study currently approved that is already in the iRIS system

Expedited

If **Yes** to registering a currently approved and paper-based study, what is the study's IRB#?
(IRB# format = xx-xx-xx or CCxxxxx)

Note:

- You do not need to register already approved determinations (NHR-XX-XX) or exemptions (EM-XX-XX) in iRIS. The registration process is intended for all other types of studies which have received regular IRB approval (i.e. clinical trials, chart reviews, discarded tissue studies, survey studies, etc.) and have IRB numbers (e.g., IRB# 01-01-01 or CC012345)
- If you have to make immediate changes to your study, or your study requires immediate continuing review, please do this via paper submission and get the approval before registering your study. Registrations may take a few weeks to process, depending on the age of the study.

8.0

Study Information and Personnel

8.1 Type of study:

Select all that apply:

- Chart Review Study
- Discarded Tissue Study
- Questionnaire/Survey Study
- Data and/or Sample Repository
- Blood Draw
- Humanitarian Use Device
- Clinical Trial
- Other (specify:)

If **Clinical Trial**, select the Phase below:

8.2 Please indicate the origin of the protocol? (Who conceived of and leads the development of the protocol regardless of funding.)

- Investigator initiated (Investigator(s) developed protocol, regardless of funding)
- Industry (Pharmaceutical, Device, etc.) (Industry developed protocol)
- Federal Agency (NIH, DOD, etc.)
- Cooperative Group (SWOG, GOG, etc)
- Other (Please specify):

8.3 Background / Rationale / Significance:

Describe the relationship of the proposed research to previous studies in the field (include pertinent references) and describe the significance of the proposed research.

Endoscopic procedures are an integral part of diagnosing and monitoring disease

processes for an array of gastrointestinal disorders in children and demand for these services is increasing (1). A retrospective chart review conducted at the Children's Hospital of Philadelphia showed that over a 20-year period from 1985-2005, the first time EGD rate increased 12-fold (5). Pediatric endoscopic procedures have evolved from a more infrequent inpatient procedure in the operating room to a routine outpatient procedure that can be conducted in multiple settings (5,9). While historically the majority of these procedures were performed at tertiary care centers, with increasing demand, more are being performed at satellite or ambulatory centers. There is interest in better understanding outcomes, efficiency and cost effectiveness of pediatric endoscopic procedures in different clinical settings, as optimizing these aspects of care would benefit the patient, physician and institution alike. While there is some literature that analyzes these aspects in a tertiary care setting, scarce literature is available that describes this at a satellite or ambulatory unit and that compares these endpoints in two different settings. This is likely at least partially due to the fact that ambulatory units are still used less commonly in the pediatric compared to adult population due to continued greater demand for endoscopic procedures in adults (8).

There is limited published data available looking at complication rates after endoscopic procedures, particularly in the pediatric world. In a study that looked at adverse events in children within 30 days after EGD, investigators found that approximately one third of patients experienced sore throat or hoarseness (13). In regards to pediatric colonoscopy outcomes, bleeding occurs in 0.26%-2.5% of patients depending on the case series (12). Perforation and bacteremia are even more rare. To date, there is no literature that compares pediatric endoscopic complication rates in different clinical settings that are part of the same institution, and understanding if there is a significant difference could ultimately improve patient care and satisfaction.

Regardless of the setting in which endoscopic procedures are being performed, there are significant costs to operating such a unit (6). Thus, maximizing efficiency in endoscopy suites is important as significant financial savings can be achieved as a result of improving workflow (3). The literature has shown varying 'rate limiting steps' at different endoscopy centers that result in decreased efficiency. This seems to be affected by multiple factors, from tardiness of physicians or patients to the ineffectiveness of the pre procedural area, and speaks to the varying nature of how endoscopy suites are run (3,9,10). In a study that analyzed 2713 endoscopic procedures, investigators found that the rate-limiting step of efficiency occurred in the pre-procedure area before patients were wheeled to the endoscopy room for the procedure itself (3). The study occurred at a large tertiary care hospital and importantly excluded adds on cases and emergent procedures. In another study that analyzed 675 endoscopic procedures performed at a tertiary care teaching hospital, investigators found that delays were most commonly physician related. Inpatient procedures tended to be more delayed than outpatient ones, and cases involving trainees were more prolonged than those that did not involve trainees (4). Due to lack of literature, it is unclear if endoscopic procedures performed at satellite or ambulatory centers would be more or less efficient compared to at tertiary care centers, but the tendency to have fewer trainees and less acute patients in these types of settings may potentially result in smoother workflow and greater efficiency (3).

The goal of this research is to better understand and compare outcomes, cost effectiveness and efficiency of pediatric endoscopic procedures at our tertiary care center, Rainbow Babies and Children's Hospital with satellite centers including St. John's Medical Center and Ahuja Medical Center, which are part of our institution. Understanding why one setting may have better outcomes and be more efficient and more cost effective than the other may help us improve resource utilization, minimize wasted financial resources and improve patient satisfaction at our institution as a whole.

8.4 Purpose / Hypothesis:

Describe the purpose of this study and provide the study aims, goals, hypothesis.

Objectives:

1. To characterize the pediatric population undergoing EGD and colonoscopy at Rainbow Babies and Children's Hospital, St. John's Medical Center and Ahuja Medical Center.
2. To characterize the outcomes including deaths, intestinal perforations, infections and unintended hospitalizations after EGD and colonoscopies at Rainbow Babies and Children's Hospital compared to those procedures at St John's Medical Center and Ahuja Medical Center
3. To determine the cost of EGD and colonoscopies to the patient at Rainbow Babies and Children's hospital compared to St. John's Medical Center and Ahuja Medical Center
4. To determine and compare the time efficiency of endoscopic procedures between Rainbow Babies and Children's Hospital, St. John's Medical Center, and Ahuja Medical Center

We hypothesize that:

1. There will be no statistical difference in outcomes of endoscopic procedures at Rainbow Babies and Children's Hospital compared to the satellite centers but the satellite centers will be more cost effective and efficient compared to tertiary care center

8.5 References:

If you have any literary references, you can list them here.

1. Day, Lukejohn W, and Belson, David. "Studying and Incorporating Efficiency into Gastrointestinal Endoscopy Centers." *Gastroenterology Research and Practice*, vol. 2015, no. 764153, April 2015, pp. 1-9
2. Dar, Abdul Q, and Shah, Zahoor A. "Anesthesia and sedation in pediatric gastrointestinal endoscopic procedures: A review." *World Journal of Gastrointestinal Endoscopy*, vol. 2, no. 7, July 2016, pp. 257-262
3. Kaushal, Neal K, et al. "Using efficiency analysis and targeted intervention to improve operational performance and achieve cost savings in the endoscopy center." *Gastrointestinal Endoscopy*, Vol. 79, No. 4, October 2013, pp. 637-645
4. Young, Elaine, et al. "Efficiency of an endoscopy suite in a teaching hospital: delays, prolonged procedures, and hospital waiting times." *Gastrointestinal Endoscopy*. Vol. 64, No. 5, 2006, pp. 760-764.
5. Franciosi, James P, et al. "Changing Indications for Upper Endoscopy in Children over a 20 Year Period." *Journal of Pediatric Gastroenterology and Nutrition*. Vol. 51, No. 4, October 2010, pp. 443-447.
6. Frakes, JT. "Outpatient endoscopy: the case for the ambulatory surgery center." *Gastrointestinal Endoscopy*, Vol. 12, No. 2, April 2002, pp. 215-227
7. Kramer, Robert E, et al. "Quality Improvement in Pediatric Endoscopy: A Clinical Report From the NASPGHAN Endoscopy Committee." *JPGN*. Vol. 65, No. 1,

July 2017, pp. 125-131

8. Pall, Harpreet, et al. "Developing the Pediatric Gastrointestinal Endoscopy Unit: A Clinical Report by the Endoscopy and Procedures Committee." *JPGN*. Vol. 63, No. 2, August 2016, pp. 295-306

9. Tomer, Gitit, et al. "Improving the Timeliness of Procedures in a Pediatric Endoscopy Suite." *Pediatrics*. Vol. 133, January 2014, pp. 428-433.

10. Mani, Jyoti, et al. "Impact of Pre-Procedure Intervention on No-Show Rate in Pediatric Endoscopy." *Children*. Vol. 2, March 2015, pp. 89-97.

11. Zamir S, Rex DK. "An initial investigation of efficiency in endoscopy delivery." *American Journal of Gastroenterology*. Vol. 97, No. 8, August 2002, pp 1968-1972

12. Friedt, Michael and Welsch, Simon. "An update on pediatric endoscopy." *European Journal of Medical Research*. Vol. 18, No. 24, July 2013, pp. 1-7

13. Samer, Ammar et al. "Complications after outpatient upper GI endoscopy in children: 30-day follow up." *American Journal of Gastroenterology*. Vol. 98, No. 7, July 2003, pp. 1508-1511

8.6 Study Performance Sites and Personnel Section

Local Performance Sites

The following must be filled out for EACH local performance site involved in the research proposed under this protocol:

"Add a New Row", select your Performance Site from the drop-down list (or type it in if not found in the drop-down) and then answer the enrollment questions. Repeat this for each site.

Performance Site	Projected Study Enrollment
UHHS- Rainbow Babies and Childrens Hospital If Other , specify: <input type="text"/>	For first year: <input type="text" value="2000"/> For entire protocol: <input type="text" value="6000"/>
UHHS- St. Johns Westshore If Other , specify: <input type="text"/>	For first year: <input type="text" value="50"/> For entire protocol: <input type="text" value="200"/>
UHHS-Other If Other , specify: <input type="text" value="Ahuja Medical Center"/>	For first year: <input type="text" value="100"/> For entire protocol:

Personnel Table

Click the gray box with a paper clip below & select "Add a New Form" under A Personnel Table Form.

If you have completed this form in the past, you can copy your previous Personnel Table by selecting "Add Revision".

No form has been associated.

8.7 Is this a multicenter study?

Yes No

If **Yes**:

Number of Enrollment Sites:

Approximate number of subjects to be enrolled at all sites for the completed protocol:

Will any local sites function as the coordinating site for this study?

Yes (list site(s) below)

No

8.8 Are human subjects at more than minimal risk?

Yes No

If **No to minimal risk**, is expedited review requested for this protocol?

Yes No

8.9 Has this study been registered on www.clinicaltrials.gov?

Yes No

Note: Phase 2 - 4 trials of drugs and biologics (controlled clinical investigations other than Phase 1 investigations of a product subject to FDA regulation) AND trials of devices (controlled trials with health outcomes, other than small feasibility studies and pediatric post-marketing surveillance) must be registered per the Food and Drug Administration Act of 2007. NIH encourages registration of all trials, regardless of

whether required under applicable law. Failure to comply with applicable rules and guidance can result in serious penalties as well as restrictions on publications.

If **YES**

Who provided the information for registration (i.e., Investigator or Sponsor)?

Please provide ClinicalTrials.gov Identifier (e.g. NCT00391872):

If **NO**

Are there plans to register the study?

- Yes, provide when below
- No, provide explanation below

No intention to register this study

8.10 Does the study use the Clinical Research Unit?

Yes No

If **Yes**, which Clinical Research Unit?

- Dahms Clinical Research Unit (DCRU) at UHCMC (Note: If you are using the DCRU, add them as an associated department in Section 2.0)
- Cleveland Clinic Clinical Research Unit
- Clinical Research Unit (CRU) at MetroHealth

8.11 Is the Principal Investigator (PI) submitting this study to another IRB?

Yes No

If **Yes**, which IRB?

- Cleveland Clinic IRB
- Louis Stokes VA IRB
- MetroHealth IRB
- Case Cancer IRB
- NCI - Central IRB
- Other:

8.12 Does this study involve cancer research or cancer-related issues?

Yes No

9.0

APPLICATION for NEW PROTOCOL LIMITED TO CHART REVIEW and/or DISCARDED TISSUE

9.1 To qualify to use this form all the following criteria must be met:

- The review uses charts at UHCMC and/or tissue from UHCMC (or from another entity where UHCMC IRB is the IRB of Record for the protocol).
- The review is limited to "research involving materials (data, documents, records, or discarded tissue specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)."
- The study is not more than minimal risk to subjects.

9.2 This request is for: (both may be chosen if appropriate)

- Chart Review
- Use of Discarded Tissue (Tissue removed after death is not subject to IRB regulations; however, HIPAA rules apply.)

9.3 Source of data for the study (check all that apply)

- Charts from the practice of the investigator or from his or her Division or group
- Charts from other physicians practices
- Charts from the UHCMC record room
- Tissue from the practice of the investigator or from his or her Division or group
- Tissue from the Department of Pathology
- Other, explain:

10.0

Request for Expedited Review of New Protocol

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or his designate without review of the protocol by the entire IRB.

10.1 Are subjects at more than minimal risk? *

Yes • No

*Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than in daily life.

10.2 If No, then the study may qualify under one of the following categories. Check one category that applies.

- Clinical studies of drugs for which an investigational new drug application 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.)
- Clinical studies of medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 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.

- Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (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) saliva collected either in a stimulated or unstimulated fashion; (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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- 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: (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.

- 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).

- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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.

11.0 Study Population

11.1 Human subjects involved are:

- Adults
- Minors (indicate ages below)

0-21

If **minors** are involved, the following question must be answered:

Provide Risk Assessment for research studies including minors (select one option):

- Not greater than minimal risk (45 CFR 46.404/ 21 CFR 50.51)
- Greater than minimal risk, but prospect of direct benefit to the subject (45 CFR 46.405/ 21 CFR 50.52) - Risk represents a minor increase over minimal risk
- Greater than minimal risk, but prospect of direct benefit to the subject (45 CFR 46.405/ 21 CFR 50.52) - Risk represents more than a minor increase over minimal risk
- Greater than minimal risk, with no prospect of direct benefit to the subject but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406/ 21 CFR 50.53) (Both parents must sign consent form.) - Risk represents a minor increase over minimal risk
- Risk represents more than a minor increase over minimal risk (45 CFR 46.407/21 CFR 50.54) (Requires Federal review)

11.2 Vulnerable Populations: Indicate all vulnerable populations that will be enrolled in this research: (select all that apply)

- Minors
 - Wards of the State
 - Foster Children
 - Neonates
 - Fetuses or abortuses
 - Pregnant Women (being recruited for study participation)
 - Pregnant Women (will be followed if they become pregnant during the course of the study - participant or partner)
 - Student of House Staff under the supervision of investigators
 - Employees of UHHS or Case
 - Prisoners

- Residents in an institution
- Severe acute illnesses associated with cognitive impairment (seizure, MI, on respirator, stroke, etc.)
- Dementia
- Mental Retardation
- Major psychiatric illness (schizophrenia, major depression, etc.)
- Illiterate Individuals
- Non-English Speaking Individuals
- NONE: No Vulnerable Populations will be enrolled in this research

Vulnerable populations: Discuss the special provisions to be made to allow the inclusion of vulnerable populations OR justify the exclusion of vulnerable populations.

It is necessary to enroll minors to answer the research question and their rights and welfare will be fully protected. There will be no direct contact with the subjects

11.3 Source of subjects for the study

- Subjects from the practice of a study investigator
 - Subjects referred or recruited from other physicians' practices
 - Subject recruitment by advertisement, flyers, web pages, etc. (Recruitment material must be approved by the IRB prior to use. Please attach any recruitment materials to this application packet prior to submission.)
 - Subjects identified from medical record room or database outside the investigator's division or group
 - Subjects studied or recruited from primary or secondary schools
 - Physician to Physician recruitment
 - Other:

11.4 Subject Population

Characterize the study population. Provide specific inclusion criteria:

Order Number	Criteria
1	Any patient between 0 and 21 years old who underwent EGD or colonoscopy at Rainbow Babies and Children's Hospital, Ahuja Medical Center or St. John's Medical Center between January 1, 2014 and February 28, 2018.

Provide specific exclusion criteria:

Order	Criteria
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Number	
1	Any patient who was above 21 years old
2	Any patient who underwent other endoscopic procedure that was not an EGD or colonoscopy
3	Any patient who underwent EGD or colonoscopy at a center outside of RB&C, St. John's Medical Center and Ahuja Medical Center
4	Any patient who underwent EGD or colonoscopy before January 1, 2014 and after February 28, 2018

Recruitment: Describe how subjects will be recruited for the proposed research study.

Patients would be identified via chart review. The list of patients who underwent esophagoduodenoscopy and colonoscopy between January 1, 2014 and February 28, 2018 will be obtained from the EMR. Charts will be reviewed and only patients who meet the above criteria will be included

Is the Principal Investigator (PI) recruiting subjects from an international site?

Yes No

If **Yes**, indicate country/countries in the table below.

Country	Additional Info (Province, Territory, etc.)
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No record has been added

Has the protocol been submitted for approval to an IRB / Ethics Committee in a foreign country?

Yes No

If **Yes**, provide the name of the IRB / Ethics Committee and the FWA

If **No**, clarify why:

Study will be performed in the USA

12.0 Subject Informed Consent / Assent / Parental Permission

12.1 *Please be sure all study personnel who will obtain informed consent have current CREC / HSP certification

Where will the informed consent process take place?

- At local performance sites

Please indicate the site(s):

- Outside of hospital/clinic setting

Please list non-medical locations:

12.2 How will informed consent be obtained? (select all that apply)

OPTION #1: Written and Signed Consent

- Written, obtained in accordance with Federal Regulations (DHHS: 45 CFR 46 and FDA: 21 CFR 50 where applicable). *Copies of all consent forms to be used must be attached to the application packet prior to submission

If **written**, list all languages that will be utilized:

If **translated consent forms** will be used, provide the qualifications of the individual or the service that was used to translate the informed consent documents.

OPTION #2: Waiver of Signed Consent

- Consent is obtained in accordance with Federal Regulations (DHHS: 45 CFR 46 and FDA: 21 CFR 50 where applicable) with a request to waive the requirement for a signed consent form.

How will consent be obtained:

- In person
- Over the telephone
- On the internet
- Other:

Will an information sheet be provided to subjects?

- Yes No

OPTION #3: Full Waiver of Consent

- Request for full waiver of requirement to obtain consent under DHHS: 45 CFR 46.

Is the study regulated by the FDA?

- Yes No

If **Yes**, requirement to obtain informed consent MAY NOT be waived unless:

1. Test article/device use is considered "Emergency Use" under FDA 21 CFR 50.23 (if yes, please re-submit to IRB under FDA "Emergency Use" provision) OR
2. research qualifies as "Emergency Research" under FDA 21 CFR 50.24

OPTION #4: Alteration of Consent Procedures

- Request for waiver of consent procedure which does not include or alters some elements required under DHHS: 45 CFR 46 (not applicable for research regulated by the FDA)

12.3 Plan for obtaining Informed Consent:

Discuss the plan for obtaining informed consent in detail.

A waiver of consent has been requested

12.4 Assent Plan for Minors (select all that apply). Only complete this section if minors are involved in the research.

- Age less than 7 years – Assent not required and waiver of assent does not need to be requested.

Request for waiver of assent:

- 7-13 years of age
- 14-17 years of age

Verbal Assent: (*The verbal assent script must be attached to the application packet prior to IRB submission)

- 7-13 years of age
- 14-17 years of age

Written assent for signed by minor: (*Copies of all assent forms to be used must be attached to the application packet prior to submission)

- 7-13 years of age
- 14-17 years of age

Written assent documented on parental consent/permission form:

- 7-13 years of age
- 14-17 years of age

Will an information sheet be used? (*Any information sheets to be used must be attached to the application packet prior to IRB submission)

- Yes No

Will you obtain parental permission for inclusion of minors?

Yes No

If **Yes**, how will you obtain permission:

- Written
- Verbal

Will you obtain the signature of one or two parents?

- Two parental signatures (required if research falls under 45 CFR 46.406/21 CFR 50.53/54; research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition)
- One parent signature (permitted if research falls under 45 CFR 46.404/ 21 CFR 50.51 or 45 CFR 46.405/ 21 CFR 50.52; research not involving greater than minimal risk or research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects)

12.5 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?

Yes No

If **Yes**, how are HIPAA privacy regulations met?

- Privacy authorization language in the consent form (stand-alone HIPAA Authorization documents should no longer be used)
- Requesting partial or full waiver of subject authorization
- Use or disclosure of PHI is preparatory to research

Explain:

The patient charts will be maintained on the EMR. The documents connecting the patient's EMR to the patients' actual number will be stored on an encrypted USB. The deidentified information will be saved to the UH RedCAP system

- Use or disclosure of PHI involves decedents' information

Explain:

13.0

Request for Waiver or Alteration of Informed Consent

13.1 This form should be completed in order to request a waiver or alteration of the consent process.

Additional guidance regarding informed consent can be found within the following Federal Regulations:
45 CFR 46.116 / 21 CFR 56.109

Please indicate which you are requesting:

- Waiver of Informed Consent
- Alteration of Informed Consent

13.2 Is the research study subject to FDA regulations* (i.e., involves use of a food, drug, biologic, device)?

- Yes ● No

* If the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application, consent cannot be waived unless the test article/device is considered Emergency Use or the research qualifies as Emergency Use. In the event of Emergency Use, return to the routing section of the application and complete the "Emergency Use" form.

13.3 Is the research (or demonstration project) subject to the approval of state or local government officials and designed to study public benefit or service programs or procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs?

- Yes ● No

If **Yes**: Please describe why the research could not practicably be carried out without the waiver or alteration of consent

If the answer to both questions above is "no", please provide the following information in order to request a waiver or alteration of consent:

13.4 Explain how the research involves no more than minimal risk.

This is a retrospective chart review. There will be no direct contact with the patients. This data will be directly entered into the encrypted USB drive.

13.5 Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants.

Data will be collected in a de-identified manner. The research will not adversely affect the rights of the subject because all information used in this research was gathered for clinical purposes and no new information will be obtained. The data will be collected in an encrypted USB drive in a locked drawer in Dr. Khalili's office on the 7th floor of Rainbow Babies and Children's Hospital.

13.6 Explain why the research could not practicably be carried out without the waiver or alteration of consent.

This is retrospective chart analysis. Contacting the patients would be tedious and unnecessary as their information will be de-identified and password protected. The medical care of the subject is complete and many have moved or changed contact information, so it would be very difficult to contact them.

13.7 Will the participants be provided with additional pertinent information after participation?

Yes • No

Describe why or why not:

At no point during the study will the participants be directly contacted.

14.0

Request for Waiver or Alteration of Assent

14.1 This form should be completed in order to request a waiver of assent for children to be enrolled in the proposed research study.

Additional guidance regarding assent can be found within the following Federal Regulations:
45 CFR 46.408 / 21 CFR 50.55

Please indicate which you are requesting:

- Waiver of Assent
- Alteration of Assent

14.2 Please complete all questions in either Section A, B or C:

Section A

Explain how the capability of some or all of the children is so limited that they cannot reasonably be consulted regarding assent.

14.3 Section B

Explain how the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

14.4 Section C

Explain how the research involves no more than minimal risk.

The research is a retrospective chart review analysis and there will be no direct patient contact. All effort will be made to protect the subjects' confidentiality.

Explain why the waiver or alteration of assent will not adversely affect the rights and welfare of the participants.

The PHI will be de-identified and stored on the UH RedCAP system. The document linking the de-identified information to the EMR will be stored on an encrypted USB drive in locked drawer in Dr. Khalili's office on the 7th floor of Rainbow Babies and Children's Hospital

Explain why the research could not practicably be carried out without the waiver or alteration of assent.

This is a retrospective chart analysis. Contacting the patients would be tedious and unnecessary as their information will be de-identified and password protected. The medical care of the subject is complete and many have moved or changed contact information, so it would be very difficult to contact them.

Will the participants be provided with additional pertinent information after participation?

Yes No

Describe why or why not

Patients will not be contacted during this retrospective study.

15.0

Request for Waiver of HIPAA Authorization

15.1

This form should be completed in order to request a waiver of HIPAA Authorization.

Additional guidance regarding HIPAA Authorization can be found within the following Federal Regulations: 45 CFR 160 and 45 CRF 164

Please indicate which you are requesting:

- Partial Waiver of HIPAA Authorization
- Full Waiver of HIPAA Authorization

15.2

This is a request to use identifiable information in the conduct of this research study under a waiver of authorization. Describe the identifiable information being requested:

Provide a description of the data to be used, in a specific and meaningful fashion. The description should be understandable; not a mere recitation of data elements understandable only to the research team. The description should be specific and the request should be limited to that information necessary to the research protocol. Examples of specific and meaningful descriptions include "Lab tests," "clinic visit data," "X-ray readings," etc.

The data to be reviewed will be: MRN, date of birth, date of procedure, gender, ethnicity, indication for EGD or colonoscopy, duration of procedure, outcomes of procedure including deaths, intestinal perforation, infection and unintentional hospitalization, cost to the patient per procedure

15.3

The proposed study cannot be done without the specified identifiable information because:

Discuss reasons why it would not be possible to conduct the research without the identifiable information being requested

This information is vital to identifying inclusion and exclusion criteria in order to create a data set to analyze

15.4 The identifiable information will be used or disclosed only by members of the research team and the following persons:

Identify with specificity and justify the need to disclose the information to any one outside UH.

The information that identifies the patients will be used by the research team while collecting the data and it will not be disclosed to anyone outside the research team or to any outsider of University Hospitals. Information will be kept in a secure password protected database.

15.5 The proposed study poses minimal risk to the privacy of the subjects because:

The identifiable information will be protected from improper use or disclosure by:

Detail how this will be accomplished including limitations of physical or electronic access to the information and other protections.

The identifiable information will be used while collecting data in an University Hospital computer that is password protected and only accessed by the research team.

The identifiers will be destroyed at the earliest opportunity consistent with the research:

Discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them.

The identifiers will be destroyed as soon as the data collection is finished and reviewed. Once statistical analysis is completed, database with identifiers will be destroyed

The identifiable information will not be reused or disclosed to any other person or entity outside UHC other than those identified in the protocol, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

Provide written assurance to this.

The identifiable information will not be re-used or disclosed to any other person or entity outside UH. The identifiable information will be just used by the research team while collecting data. The identifiable information will not be reused or disclosed to any other person or entity outside UH other than those identified in the protocol, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB

15.6 The proposed study cannot be practicably conducted without a waiver of authorization because:

Discuss reasons why it would not be possible to obtain authorization from individual subjects.

The medical care of the subject is complete and many have moved or changed contact information, so it would be very difficult to contact them.

16.0 Study Procedures

16.1 Select all research-related procedures done as part of this protocol (select all that may apply):

- Blood drawing
- Specimen removed at surgery (collection/use)
- Biopsy of tissue
- Urine collection/use
- Stool collection/use
- Saliva collection/use
- Drug / Biologic Administration - Investigational
- Drug / Biologic Administration - Not Investigational
- Placebo Administration
- Washout
- Genetic testing
- Questionnaires
- Deception/Incomplete disclosure
- Radiation exposure
- Device utilization/implementation - Investigational
- Device utilization/implementation - Not Investigational
- Electrical device
- Medical Record Review - Hard Copy
- Medical Record Review - Electronic
- Use of Stem Cells
- Other (specify)

cost of procedures from UH administration

16.2 Please indicate if the proposed research involves study staff performing any of the following procedures that require special training. (Select all that apply)

- Collection, handling and/or processing of biohazardous samples (blood, urine, tissue, etc.)
- Preparing blood, tissue or other samples for shipment
- Working with Laboratory Chemicals
- Working with Formalin/Formaldehyde
- Exposure to Radioactive Materials
- Working with radiation generating equipment (X-rays, etc.)
- Exposure to Lasers
- Use of a Respirator
- Chemotherapy Administration
- NONE: None of the above procedures will be performed

If any of the above were selected, all research staff must have received the proper training before working with such materials.

For more information regarding training, please contact UH's Office of Research Compliance and Education or CWRU's Department of Occupational and Environmental Safety.

16.3 Genetic Testing

a. Is obtaining blood, tissue or saliva samples for genetic testing included in this protocol?

- Yes No

If **Yes**, please provide additional discussion of the genetic testing components including who will conduct the tests. Also, be sure that your consent form discusses study subjects' options re: genetic testing and the risks associated with genetic testing.

b. Will NIH Genome-Wide Association Studies (GWAS) be conducted?

- Yes No

If **Yes**,

Will you be sending samples/data to the NIH GWAS?

- Yes No

Will you be using sample/data obtained from the NIH GWAS?

- Yes No

Please provide justification for using NIH GWAS:

16.4 Does the protocol include gene therapy?

- Yes No

If **Yes**, the protocol must receive approval from Case Western Reserve University's Institutional Biosafety Committee (IBC) prior to IRB submission. The IBC application and approval letter must be attached to the IRB application packet prior to submission.

16.5 Does the research involve the use of radiation or radioactive substances?

- Yes No

If **Yes**:

a) Is the radiation use only for the purposes of the research study (e.g. over and above standard of care)?

- Yes No

If **Yes**, the protocol must receive approval from the Radiation Safety Committee (RSC) prior to IRB submission.

The RSC application and approval letter must be attached to the IRB application packet prior to submission.

b) Does the protocol use radionuclides?

- Yes No

If **Yes**, the protocol must receive approval from the Radiation Safety Committee (RSC)

prior to IRB submission.

The RSC application and approval letter must be attached to the IRB application packet prior to submission.

c) Provide justification for the additional risk associated with the research radiation use.

16.6 Does the protocol include electrical devices not approved for clinical use?

Yes No

If **Yes**, the protocol must receive approval from the UHCMC Electrical Safety Committee prior to IRB submission. The Electrical Safety Committee approval letter must be attached to the IRB application packet prior to submission..

16.7 Does the protocol require approval by an Intensive Care area?

Yes No

If **Yes**, an Intensive Care approval letter must be attached to the IRB application packet prior to submission..

17.0 Study Procedures – Drugs and Devices

17.1 Drug Administration:

a. Indicate all the drugs used during the conduct of the research (list all medications regardless of whether they are considered "investigational").

<input type="checkbox"/>	View Details	Drug Name	FDA Approved	A new drug or a new use of approved drug:	IND Number
No drugs have been added to this Study					

b. Does the study include the administration of a study agent that does not require FDA approval and does not require an IND? (e.g. vitamins, food supplements, isotope tracers, alternative medicines, etc.)?

Yes No

If **Yes**, list all agents:

c. UH Investigational Pharmacy must be utilized for all research protocols involving the administration of investigational medications. Are you using the Investigational Pharmacy (aka Investigational Drug Services (IDS))?

- Yes (Note: If you are using IDS, add them as an associated department in Section 2.0)
- No
- Not Applicable - Investigational Drug(s) Not Being Used

If **No**, a copy of the approved "**UHCMC Investigational Drug Services Exception Request Form**" must be attached to the IRB application packet prior to submission. This document can be attached in the "Other Study Document" section of the application packet.

***Please be sure to attach any Investigator Brochure documents to the application packet prior to submission.**

17.2 Device Utilization:

View Details	Device Name
No devices have been added to this Study	

For any devices being used, please list below and indicate Category A or Category B.

See help link for information re: categories and Medicare coverage of medical devices.

Device Name	Category A or Category B
No record has been added	

18.0 Study Procedures – Descriptions

18.1 Study Design / Site Specific Study Procedures:

Discuss how the study will be conducted at this site including a description of the intended treatment plan and/or procedures.

This study is a retrospective chart review looking at the outcomes, efficiency and cost effectiveness of pediatric endoscopic procedures including esophagoduodenoscopies and colonoscopies performed at Rainbow Babies and Children's hospital and satellite centers including St. John's Medical Center and Ahuja Medical Center. Charts from will be reviewed from the EMR that meet the specified inclusion criteria from 2014 to 2018.

The data to be collected will include demographics, age, gender, indication of procedure, duration of procedures, outcomes including deaths, intestinal perforations, infection, unintentional hospitalizations as well as cost of endoscopic procedures that will be obtained from UH administration. We expect to review at least 6000 charts. The data will start to be collected as soon as the IRB is approved and we estimate that the collection time will be 6-12

months.

18.2 Risks:

Describe all known or potential risks, discomforts and/or inconveniences to subjects.

The study possess lower than minimal risk for patients. The possible potential risk is a breach of confidentiality of the medical record information and associated privacy of the participants. We will minimize the above described by not keeping HPI information, de-identifying data, and keeping information on a UH password protected computer and secure, encrypted USB drive in a locked drawer and Dr. Khalili's office on the 7th floor of Rainbow Babies and Children's Hospital.

18.3 Benefits:

Describe the potential benefits to subjects enrolled in the proposed research.

Although there is no direct benefit to the participatnts in this study, there is hope that this study will benefits in the future.

18.4 Alternatives to Participation:

Discuss subjects' alternatives to participating in the proposed research study.

Due to the nature of the study, there are no alternatives to participation. A waiver of consent as been requested.

18.5 Withdrawal from study participation:

Describe possible causes for subjects to be withdrawn from the proposed research (such as withdrawn by PI or subject withdraws from participation) and describe procedures for following subjects after study withdrawal.

Data has been already collected in a chart review study, so ongoing participation or withdrawal will not occur. Participants will either meet inclusion criteria and have their data included in the databse, or not meet inclusion criteria and not be considered further for research purposes. Clinical services will not be affected by participation status in this study

18.6 Plans for subjects at the end of the protocol:

For treatment studies describe how subjects will be transitioned to usual medical care:

There is no plan for the subjects enrolled in the study at the end of the protocol since this would be a retrospective chart review.

19.0 Data and Safety Monitoring

19.1 Describe the Data and Safety Monitoring Plan for the proposed study.

PIs will meet monthly while data collection is taking place for safety monitoring. Dr. Khalili will monitor the data to ensure scientific integrity of the data collected and to ensure the accuracy and collection are in compliance with the protocol. The data will be monitored at first EMR querying and monthly thereafter until all necessary data is collected and analyzed

19.2 Is there a formal Data and Safety Monitoring Board/Committee?

Yes No

If **Yes**, provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports etc.

20.0 Data/Sample Confidentiality - Data/Sample Security - Subject Privacy

20.1 How will data be maintained?

- Hard Copy subject files
- Electronic subject files

20.2 How long will research data be stored by the PI after closure of study?

3 years per UH policy

20.3 Subject privacy:

Discuss provisions to protect subject privacy. Privacy is an individual's right to seclude themselves or information about themselves.

Only the investigators will have access to the names and medical record numbers of the patients involved in the study. Names and identifying information will be kept on a linking sheet, separate from the data. All the identifiers will be used while collecting data and not used for any analysis of data or publications. Every effort will be made to maintain subject privacy. The principal investigator will make sure that the identifiable information is kept under locked conditions at all times and only available to the investigators. Charts will be reviewed in a private room with the door closed and will be protected against viewing by any person either not on the study team or not currently caring directly for the subject. We will prevent discussion outside closed doors regarding

any information pertaining to data collected. Once the PHI is no longer needed (after collecting and analyzing data) the PI will make sure that it is destroyed and that no PHI is available in any publication that may result from this study.

20.4 Data/Sample confidentiality:

Discuss how the confidentiality of the data/samples being collected will be maintained.

Confidentiality will be protected by not keeping any identifying data in the database. A unique code will link the de-identified data set to the identifying data, specifically medical record numbers. Names and identifying information will be kept on a linking sheet, separate from the data. Access to the identifiers and the database will be limited to the investigators. After collecting data the identifiers will be destroyed.

20.5 Data/Sample security:

Discuss the physical elements of security, including where and how data/samples will be stored, who will have access to the data/samples and how data/samples will be accessed.

The linking database containing PHI will be kept under lock at all time within a secure USB drive that is password protected provided by UH in possession of principal investigator. The de-identified database will be maintained in a secure excel sheet on a UH password protected computer and on a UH encrypted USB drive. The only individuals who have access to the data will those involved in the study, specifically, Erin Crawford, MD, Ali Khalili, MD and Thomas Sferra, MD

21.0 Data Analysis Plan

21.1 Describe the statistical/analytical methods to be used in the proposed research study. This should include a statement about the statistical power of the study in order to test the major hypothesis.

The study participants and their data will be described using means and percentages. The sample size is based on our primary aim and the study's first purpose, creation of the database. We will use multivariate regression to assess whether there are any statistically significant differences to efficiency, cost and outcomes. Differences between groups means will be analyzed using T-test, chi-square depending on the variance to be analyzed

22.0 Financial Information

The following information must be consistent with the contract, grant, or other funding arrangements and the Coverage Analysis. Where appropriate, please ensure that the items noted below are accurately reflected in the consent

22.1 Subject compensation and remuneration:

Will subjects receive incentive, reimbursement or compensation for participation?

Yes • No

If **Yes**, check all that apply:

Reimbursement for expenses

Amount/type:

Monetary payment for time and discomfort

Amount:

Other:

Amount:

22.2 Payments to Subjects:

Discuss both reimbursement (compensation for expenses e.g., parking, meals) and incentives (payment for discomfort). Describe the payment schedule and payment total.

There will be no incentives for participants

22.3 Cost to Subjects:

Describe and justify any costs subjects will incur as a result of participation in the proposed research study.

Please ensure that the items noted below are accurately reflected in the consent document. Cost information must reflect the Coverage Analysis. Please contact the UHCMC Grants and Contracts Office (216-844-5527) for information regarding a Coverage Analysis if not already completed. Not all projects (e.g. chart reviews, registries) require a Coverage Analysis.

This study will incur in no cost to the participants.

22.4 Compensation for Research Related Injuries:

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury.

This is retrospective chart review and no research related injury is expected.

Select the consent language regarding who will pay for the costs of medical treatment and/or compensation in the event of a research related injury.

Option #1 - Funding Agency is providing any payment for injury:

- Select this text if the funding source will cover the cost of study related injury, OR the funding source will cover the cost of the study related injury if the subject's insurance will not cover the cost.

In the event that a research activity results in injury, you/your medical insurance may be charged for the cost of diagnosing and treating your condition. You may be responsible for co-pays or deductibles. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". If you/your insurance company does not pay the cost of diagnosing and treating your condition, the cost will be covered by (INSERT INDUSTRY NAME, OR OTHER ORGANIZATION PROVIDING FUNDS TO COVER THE COST OF AN INJURY) if they agree the injury was caused by the research or research activity as described in the Protocol and not the fault of the researchers or study staff. There are no plans for payment for lost wages or other expenses. To help avoid injury, it is very important to follow all study directions.

Option #2 - Funding Agency is providing no payment for injury:

- Select this text if the funding source will not cover the cost of study related injury.

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Option 3 - Not Applicable:

- No consent form is being used and/or project involves prospective collection of data/samples that involves consenting but there is no possibility of research related injury.

22.5 Study Funding

Indicate if the source of funding is used
Department/ Internal Support <input checked="" type="radio"/> Yes <input type="radio"/> No
Federal-CTSC <input type="radio"/> Yes <input checked="" type="radio"/> No
Federal-NIH <input type="radio"/> Yes <input checked="" type="radio"/> No
Federal -Other <input type="radio"/> Yes <input checked="" type="radio"/> No

Industry ○ Yes ● No
Foundation/ Association ○ Yes ● No
Local Government ○ Yes ● No
State Government ○ Yes ● No
Other Sponsor Agreement ○ Yes ● No

Is the study funded by the Department of Defense?
○ Yes ● No

Specify your funding in the section below.

If you have department funding, enter the name of your department and choose "Department Operating Account".

View Details	Sponsor Name	Sponsor Type
+	None	Other Sponsor Agreement
Sponsor Name:		None
Sponsor Type:		Other Sponsor Agreement
Sponsor Role:		

If applicable, enter Agency or Sponsor's Grant # or Contract/Protocol #:

Please Note: Any clinical trial utilizing Departmental / Internal support must have a completed, signed and approved "Internally Funded Research" form submitted to the Research Finance Specialist team as per policy R-41.

Please note: If your trial involves clinical patient care, it will be

assessed by the CCRT Research Finance Specialist team to determine the need for a Coverage Analysis (CA). Documentation of an approved clinical budget and CA will be required for the release of the Informed Consent.