PROTOCOL TITLE:

Laryngeal mask airway versus endotracheal intubation for laparoscopic inguinal hernia repair (LMA in Lap Hernia)

PRINCIPAL INVESTIGATOR:

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IND/IDE NUMBER: N/A

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Version 3 *Date:02/12/23*

REVISION HISTORY

This Revision History table is provided for the benefit of study team version control. If this table will not be useful please delete it.

Revision #	Version Date	Summary of Changes	Consent Change?
1	1/10/2023	Initial IRB submission	N/A
1.1	1/26/2023	Addressed ORI clarifications	N/A
2	7/3/2023	Add Spanish speakers	Translation
3	02/12/2024	Sample size modification	N/A

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STUDY INFORMATION

1.0 Study Summary

Study Title	Laryngeal mask airway versus endotracheal intubation for laparoscopic inguinal hernia repair
Study Design	Prospective Randomized
Primary Objective	Evaluate the effectiveness of LMA versus ETT for patients undergoing laparoscopic inguinal hernia repair by measuring SpO2 at 3 standardized timepoints
Secondary Objective(s)	1. Evaluate EtCO2 in both groups at three standardized timepoints 2. Evaluate peak airway pressures in both groups at three standardized timepoints 3. Documentation of laryngospasm occurrence in both groups
Study Population	12 mo- 8 yo patients undergoing laparoscopic inguinal hernia repair at CMH or CMK
Study Duration for Individual Participants	Single visit during which inguinal hernia repair is performed
Study Specific Abbreviations/ Definitions	LAR – Legally Authorized Representative LMA – Laryngeal Mask Airway ETT- Endotracheal tube

2.0 Objectives*

2.1 Purpose, specific aims or objectives: *Describe the purpose, specific aims, or objectives. If more than one objective be sure to list separately.*

This study aims to evaluate the effectiveness during general anesthesia of laryngeal mask airway versus endotracheal tube for laparoscopic inguinal hernia repair.

2.2 Hypothesis: Use of laryngeal mask airway is not inferior to the use of endotracheal intubation for patients undergoing laparoscopic inguinal hernia repair.

3.0 Background*

3.1 *Describe the relevant prior experience and gaps in current knowledge.*

Children undergoing laparoscopic inguinal hernia repair typically received general anesthesia with endotracheal intubation. There are limited studies looking at the use of laryngeal mask airway for short laparoscopic procedures in pediatric patients.[1,2]

3.2 *Describe any relevant preliminary data.*

There are limited pediatric literature evaluating the use of laryngeal mask airway for laparoscopic procedures compared with traditional endotracheal intubation.[1] This study aims to add to this literature in providing information comparing the two techniques.

3.3 *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.*

The rationale for this study is to show that general anesthesia with laryngeal mask airway is an effective and non-inferior technique compared with general anesthesia with endotracheal intubation in pediatric patients undergoing laparoscopic inguinal hernia repair and may offer benefits in terms of efficiency of care and respiratory complications.

References

1. Nevešćanin A, Vickov J, Elezović Baloević S, Pogorelić Z. Laryngeal Mask Airway Versus Tracheal Intubation for Laparoscopic Hernia Repair in Children: Analysis of Respiratory Complications. *J Laparoendosc Adv Surg Tech A*. 2020;30(1):76-80. doi:10.1089/lap.2019.0382
2. Asida SM, Ahmed SS. Ease of Insertion of the Laryngeal Mask Airway in Pediatric Surgical Patients: Predictors of Failure and Outcome. *Saudi Journal of Anesthesia.* 2016;10(3):295-300. doi: 10.4103/1658-354X.174898

4.0 Study Endpoints

4.1 *Describe the primary and secondary study endpoints.*

The primary endpoint of this study will be SpO2 measured at 3 standardized timepoints.

Secondary endpoints will include:

- SpO2 less than 90%
- End tidal CO2 measurement at 3 standardized timepoints
- Peak airway pressures measured at 3 standardized timepoints

- Occurrence of laryngospasm

4.2

The safety endpoint would be conversion to general endotracheal anesthesia.

5.0 Study Design*

5.1 Study Design: This will be a single institution prospective randomized study. Patients preparing for laparoscopic inguinal hernia repair (and meeting other inclusion criteria), whose parent or LAR provides permission to participate in the study, will be randomized to receive either general anesthesia with laryngeal mask airway placement or endotracheal tube placement and their data will be recorded. Patients who choose not to participate will be given either standard treatment per their assigned anesthesiologist.

5.2 Table of Events: *n/a*

6.0 Study Interventions*

6.1 Description: In this study, patients will undergo general anesthesia for laparoscopic inguinal hernia repair. The study intervention being evaluated is the placement of laryngeal mask airway instead of endotracheal intubation. Both LMA and endotracheal intubation are standard care anesthesia practices at CMH for various procedures, including sometimes laparoscopic hernia repair. This study will randomize the airway, but all other anesthesia drugs and procedures remain the same in both groups.

6.2 Behavioral Intervention*:* N/A

6.3 Drugs, Biologics, or Devices: No experimental drugs or devices will be used in this study.

PARTICIPANT MANAGEMENT

7.0 Inclusion and Exclusion Criteria*

7.1 Eligibility Criteria:

1. **<u>Inclusion Criteria</u>**

   1. Patients undergoing laparoscopic inguinal hernia repair.
   2. Ages 12 months to 8 years of age

3. American Society of Anesthesiologists Physical Status Classification ASA 1 or 2
    1. ASA 1- A normal, healthy patient
    2. ASA 2- A patient with mild systemic disease
4. Elective with appropriate NPO status
5. English speakers

2. <u>Exclusion Criteria</u>

1. Patients with current gastroesophageal reflux

2. Obesity (CDC >= 95th %ile)

3. Contraindications to study protocol medications

7.2 Equitable Selection*: Inclusion/exclusion criteria should be both fair and appropriate to the research question. If the study involves inclusion/exclusion criteria based on demographic characteristics such as sex, race/ethnicity, language, provide rationale for the criteria. For example, if excluding non-English speaking participants, provide rationale for why it is not possible to include non-English speaking participants.*

Due to the limited sample size of patients enrolled, there is little to no anticipation of enrolling a non-English speaking patient. If a non-English speaking patient arises, the proper modifications will be put in place to present patient with translated consent forms and protocol, if need be.

7.3 Vulnerable Populations: *Check any vulnerable populations <u>that are being targeted</u> for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☒ Children/Minors (under 7 years of age)
☒ Children/Minors (7-17 years of age)
☐ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☐ Wards of the State
☐ Fetuses
☐ Pregnant Women
☐ Adults with impaired decision-making capacity

☐ CM Employees
☐ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

8.0 Local Number of Participants

8.1 *Indicate the total number of participants or charts to be enrolled locally as well as the accrual goal. If the study includes multiple groups or cohorts, be sure to describe the number of participants required for each cohort. If one of the groups includes a chart review, each chart is considered a participant and needs to be reflected in the numbers below.*

	Group 1	**Group 2** (if applicable)	**Totals**
Enrollment Goal: *Number of participants to be enrolled = the number of participants to be consented or to be screened for chart reviews.*	25*	25*	50*

**The total enrollment goal will remain 50 patients, but an additional 20 patients will be enrolled to accommodate screening failures and withdrawals.*

9.0 Identification and Recruitment of Potential Participants*

9.1 Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☒ Chart reviews

☐ By their treating physician who will then provide the study team's contact information to the potential participant/family

☐ By their treating physician who will obtain patient/family permission to share contact information with the study team

☐ Self-refer in response to IRB approved advertisements or websites

☐ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☐ List of candidates provided through the Data Report Request Form

☐ Registry of individuals interested in research opportunities

☐ Past participant list

☐ Participants will roll-over from another research study: Study #

☒ Other: By treating provider, such as anesthesiologist or APRN, who is also a study team member, and who will discuss study with parent(s) and obtain informed consent (parental permission).

9.2 Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☐ Yes

☒ No

- *If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete* ***Addendum E: Waiver/Alteration of HIPAA Authorization***

9.3 Recruitment of Potential Participants:

Parents of eligible patients presenting for laparoscopic inguinal hernia repair and being treated by a member of the study team, will be presented with information about the study prior to beginning anesthesia when completing the preoperative evaluation. Electronic medical records will be accessed to deem patients eligible. Parents will be given time to ask questions and consider whether to enroll their child in this study.

10.0 Surveys and Psychometric Testing:

- N/A

11.0 Additional Study Activities

- Additional study activities will include secondary data use – recording data from the medical record after the procedure is complete.

11.1 *Blood and Other Specimen Collection:*

1. N/A- no blood or other specimens will be collected for this study.

12.0 Follow-up

- N/A- no follow up is planned as part of this study.

13.0 Genetic Analysis Information

N/A- no genetic analysis is planned as part of this study.

14.0 Sharing of Results with Participants

14.1 There are no plans to share results of the study with the participants, as their procedures will be complete before data is analyzed and results are available.

15.0 Risks to Participants*

15.1

- This study involves no greater than minimal risk to participants, as the risks are similar to those that patients would encounter undergoing general anesthesia for a procedure. Both LMA and ETT are commonly used standard anesthesia practices for various procedures.
- There is also minimal risk to privacy associated with the chart review aspect of this study. All data will be stored securely on the CMH network and in REDCap. Only IRB-approved study team members will have access to the data.

15.2 This study involves no greater than minimal risk.

15.3 N/A

15.4 N/A

15.5 N/A

16.0 Potential Benefits*

16.1 Potential benefits include:

Potentially decreased time in operating room for LMA group. Potential benefit of avoiding ETT and possible decreased risk of respiratory complications. Possible

decrease in laryngospasm, bronchospasm, and postoperative respiratory complications.

17.0 Investigator Assessment of Risk/Benefits Ratio*

17.1 *Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.*

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☐	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

18.0 Payment, Reimbursement and Tangible Property provided to participants*

Is payment, reimbursement, or tangible property part of the study?

☐ Yes ☒ No *(If No, delete the following subsections)*

19.0 Compensation for Research-Related Injury

19.1 This study is internally funded, involves no more than minimal risk and there is no planned compensation available in the event of research related injury.

20.0 Economic Burden to Participants

20.1 There are no costs to patients directly related to participation in this study. Patients or their insurance will be billed for anesthesia received for their procedure whether enrolled in this study or not.

21.0 Parental Permission and Adult Consent Process*

21.1 Indicate below all methods of Permission/Consent that will be used in this study.

- *If the study includes **multiple study groups**, be sure to indicate which method is being used with each group.*
- *If requesting a **Waiver of Documentation**, a complete **Waiver**, or an **Alteration**, complete the required addendum at the end of this document.*

Written Informed Permission/Consent

☒ **Written informed permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: Parent/LAR of participant

☐ **Written informed consent of adult participants**

Study group(s) to which this method applies:

☐ **Written informed consent of participants turning 18**

This includes the continued access to and use of their PHI by the study team.

Study group(s) to which this method applies:

Waiver or Alteration of Permission/Consent

Parent/LAR permission/adult consent will **NOT** be obtained, or an alteration to an element(s) of consent.

Must complete *Addendum B: Waiver of Permission/Assent/Consent*

☐ **Waiver/Alteration of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies:

☐ **Waiver/Alteration of consent of adult participants**

Study group(s) to which this method applies:

☒ **Waiver/Alteration of consent of participants turning 18**

Study group(s) to which this method applies:

21.2 Permission/Consent/Consent at 18 Discussion: *If selected options for "Written" or "Waiver of Documentation" above, describe below how the informed permission/consent discussion will be conducted. Describe:*

- *Where and when the discussion will take place.* The informed permission discussion will take place at CMH on the day of surgery. A study team member, likely an Anesthesia APRN, will meet with the family prior to the child starting anesthesia, and will discuss the study with the parents.
- To reduce coercion and undue influence, parents will be informed that their decision whether to participate in this study will not impact their child's care at CMH. If they choose not to participate, their child will receive standard care general anesthesia for their hernia repair.
- eConsent will be used as an option for obtaining consent, which could reduce the possibility of clerical errors on consent forms while also helping to provide access to consent records between study teams in both Surgery and Anesthesia departments involved in this study
- Study staff will try to meet with parents early enough before the procedure to allow time for parents to ask questions and consider enrollment decisions before needing to proceed with anesthesia and surgery procedures.
- Study staff will ensure that parents understand what the study involves by incorporating techniques such as the teach-back method (asking parents to explain their understanding of the study before signing the consent form).
- N/A- telephone permission/consent will not be used.

21.3 Documentation of Permission/Consent/Consent at 18: *If selected "Written" options above, explain how informed permission will be documented. Describe:*

- Informed permission will be documented in the medical record according to CM Research Policy "10.04 Obtaining Permission/ Assent/ Consent" and "Research Documentation in the Electronic Health Record."

21.4 Identification of participants turning 18: We are requesting a Waiver of Consent at 18 (see Addendum B). This study will only enroll patients up to age 8. We do not anticipate that this study will continue for 10 years or more, until the time the oldest potential participants could turn 18. Although the study will be closed by then, we are requesting a Waiver of Consent at age 18 to be able to

continue to retain data from this study in our Department of Surgery Data Repository (DSDR) after participants turn 18.

22.0 Assent of Pediatric Participants

22.1 Select the option(s) that apply to the study:

☒ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.**
Study group(s) to which this method applies: Participants aged 7 and above/deemed able and willing to understand in order to assent

☒ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

- ☒ *The capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*
- ☐ *The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

Study group(s) to which this method applies: Participants under the age of 7/deemed unable to understand in order to assent.

☐ **Obtaining assent of pediatric participants is NOT PRACTICLE given the context of this study** (e.g., minimal risk, no direct contact with participants). **Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent***

☐

22.2 Assessment of Ability to Assent: The study team member conducting the consent discussion will also discuss the study with patients age 7 or older and will check their understanding of the study.

22.3 Assent Discussion: *If seeking assent from pediatric participants, explain how the assent discussion will be conducted. Describe:*

- *The assent discussion will take place in conjunction with the informed consent discussion with parents prior to surgery.*
- *Study team members will inform and reassure patients that they can decide not to participate in the study, and this decision will be respected.*
- *Patients will be given the opportunity to ask any questions they might have, in addition to any other questions asked by parents.*

- *Study team members will verify understanding using techniques such as "teach back."*

22.4 Documentation of Assent or Inability to Assent: *If seeking assent from pediatric participants, explain how assent, or a determination of inability to assent, will be documented. Describe:*

- *CM Research Policy "10.04 Obtaining Permission/ Assent/ Consent" and "Research Documentation in the Electronic Health Record" will be followed.*
- *E-Consent will be used to document assent.*

23.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

- The past, present or future physical or mental health or condition of an individual;
- The provision of health care to an individual; **OR**
- The payment for the provision of health care, **AND**

identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

23.1 HIPAA Authorization

Select all applicable methods of HIPAA Authorization that apply to this study.

☒ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)

☒ Partial Waiver of HIPAA Authorization (e.g. waiver for recruitment and pre-screening purposes only)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

☐ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g. signature will not be obtained)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) Describe which proposed elements to be altered.

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained)

☒ If Other, explain: We are requesting a Waiver of HIPAA Authorization at age 18 to allow data to continue to be retained in the DSDR without reconsenting former participants who have since turned 18. See Addendum E.

23.2 Specify the PHI for which accessing ("viewing") or recording ("writing down") is necessary for the purpose of this research:

To minimize risks, only the minimum necessary identifiable data should be accessed and/or recorded.

1. Name/Initials	☐ Accessed only	☒ Recorded
2. All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded
3. Medical record number	☐ Accessed only	☒ Recorded
4. Account number	☐ Accessed only	☒ Recorded
5. Health plan identification number	☐ Accessed only	☐ Recorded
6. Social Security Number	☐ Accessed only	☐ Recorded
7. Device identifiers and serial number	☐ Accessed only	☐ Recorded
8. Certificate/License number	☐ Accessed only	☐ Recorded
9. Telephone number	☐ Accessed only	☐ Recorded
10. Fax number	☐ Accessed only	☐ Recorded
11. Email addresses	☐ Accessed only	☐ Recorded
12. Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☐ Recorded
14. Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
15. Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
16. Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded
17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)	☐ Accessed only	☐ Recorded
18. Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
19. Other:	☐ Accessed only	☐ Recorded

23.3

The confidentiality of data will be protected by recording data in REDCap securely on the CMH network servers, by allowing access only to study personnel approved by the IRB to work on the study, and by storing Master List identifiers (Name and MRN) on a separate form than the study data.

23.4

No Certificate of Confidentiality will be issued for this study.

24.0 Provisions to Protect the Privacy Interests of Participants*

24.1

The Permission/Assent/Consent discussion will take place in a private room with only the parent(s) and study team members present, to ensure privacy during the P/A/C process.

24.2 Study team members conducting the Permission/Assent/Consent discussion with families will be trained to ensure parents that participation in the study is completely voluntary and not required for their treatment, and to encourage parents to ask questions about the study to help them feel at ease.

24.3 The study team members conducting P/A/C discussions will have access to information about these patients, as they will be encountering them as part of the standard clinical treatment planned for these patients. They will ensure privacy of this information as required for any other clinical information about patients.

25.0 Withdrawal of Participants*

25.1 We do not anticipate any circumstances under which participants would be withdrawn from the study without their consent, however the procedure may change after consenting, either due to surgeon preference of unforeseen circumstances, that would therefore exclude your child from research.

25.2 If a parent chooses to withdraw their child from the study, any data collected about the child will be retained in the study unless the parent requests to have the data excluded from the study.

DATA MANAGEMENT

26.0 Data Collection*

26.1 Data collected during the study will include data about the hernia repair procedure outcome and about the encounter in general (e.g., length of stay, comorbidities impacting length of stay).

26.2 Data will be obtained from the medical record after the hernia repair procedure is completed.

26.3 N/A

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27.0 Adverse Events and Unanticipated Problems*

27.1 Monitoring:
27.2 There are no Adverse Events or Unanticipated Problems associated with this study, as the LMA and ETT techniques being evaluated are already used in current standard care. As when these techniques are used in current standard care, the Anesthesia team will closely monitor patients during the procedure and will modify anesthesia if clinically warranted.

27.3 Reporting: We will follow Policy 5.11 Reportable Events of the CM Research Program Policies and Procedures in regards to reporting adverse events and other unanticipated problems to the CM IRB.

28.0 Statistical Analysis*

28.1 The data analysis will be a simple calculation of demographics and incidence of complications. Comparison between groups will be completed using chi square for categorical variables and t-test for continuous variables. Statistical significance will be set at p-value <0.05

We determined the targeted sample size of 50 patients using a power calculation using the following parameters: 90% power, 2.5% Type I error rate, non-inferiority limit of 5% point of SP02, no difference between treatments, and standard deviations of 1, 2, 5, and 10.

29.0 Data and Specimen Management*

29.1 Data Management: *Describe how data will be handled, including:*

Data will be collected by reviewing the participant’s medical record after the circumcision procedure is complete. Data will be recorded in REDCap, securely stored on the CMH servers, and only accessible to IRB-approved study team members. Data will be rolled into the

Department of Surgery Data Repository (DSDR, IRB#18020079) at the time of data collection, and will remain stored in the DSDR under the approved provisions of the repository for potential use in future research studies.

29.2 Specimen Management: *Describe how specimens will be handled, including:*

1. N/A

29.3 Biosafety Information

Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

If processing potentially hazardous biological materials, where will this work be conducted?

☐ Pediatric Clinical Research Unit (PCRU)

☐ Children's Mercy Research Institute Biorepository (CRIB)

☐ Children's Mercy Research Institute labs (mySafety ID#:_____)

☐ Other location

If "Other location," identify the location and mySafety ID# of the corresponding IBC protocol:

Location: _____

mySafety ID#: _____

30.0 Storing of Data and/or Banking of Specimens for Future Research

30.1 *If this study involves storing of data or banking of leftover specimens for future research, indicate how the use will be managed:*

☒ Contributing data and/or leftover specimens to an existing CM repository protocol (myIRB#18020079, Department of Surgery Data Repository (DSDR))

☐ Contributing data and/or leftover specimens to an existing non-CM repository (Institution/Repository Name: _____)

☐ Not contributing to an existing repository for the management of data/specimens for future research use.

☐ Other:

31.0 Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants.

31.1 *In addition to the Principal Investigator, which individual or group will be responsible for monitoring the data and safety for this study?*

☐ Sponsor or Sponsor Designee (including the Sponsor CRO)
☐ Data and Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC)
☐ Independent Monitor (s)
☐ Internal Committee at CM
☒ Other: ____N/A_____

31.2 Data Safety Monitoring Plan: *If a DSMB charter or other external monitoring plan is available, upload in the myIRB application, Other Attachments section. If such a charter/plan is not available, describe:*

1. There are no plans for a DSMB for this study.

STUDY MANAGEMENT

32.0 Setting & Locations*

32.1 *Describe the sites or locations where the research will be conducted.*

1. Participants will be recruited when present for hernia repair procedures at CMH or CMK. Data collection and study coordination will also take place in the offices of the General Surgery department at CMH.

33.0 Multi-Site Research- N/A

Choose ALL relationship types that apply:

☐ ***Multi-Site Research:*** *Multiple sites will be engaged in this human research project. Sites will use the* ***same*** *protocol to conduct the* ***same*** *human research activities (except for minor variations due to local context considerations).*

☐ ***Collaborative Research:*** *Multiple sites will be engaged in this human research project. Sites will* ***not*** *be performing the* ***same*** *research activities. The Site submission will specify the specific research activities each site will perform.*

REQUIRED*: Enter summary of site-specific activities that differ from the overall protocol:* Click or tap here to enter text.

☐ ***Student(s)*****:** Student(s) will help with this project and will be engaging their home institution.

☐ **Visiting *Resident(s) /* Visiting *Fellow(s)*:** Visiting Resident(s) / Visiting Fellow(s) will help with this project and will be engaging their home institution.

Is Children's Mercy (CM) acting as the single IRB of Record (sIRB)?

☐ ***No, each site is getting their own IRB approval.***

☐ **Yes, some or all sites will rely on the CM as the sIRB**.

- ***Reliance is required*** *for non-Exempt* ***NIH*** *or other* ***Federally Funded*** *research where:*
  - *The institution's employees or agents intervene or interact with human subjects for research purposes;*
  - *The institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or*
  - *The institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.*

If CM is sIRB for another site, complete the chart for that site(s) (*Add a new row for each site relying on the CM IRB, delete chart if not acting as sIRB):*

Site Name	Enrollment Goal for Site(s) *Choose One*	Relying on CM IRB?
Insert Site Name	☐ **Site Enrollment Goal:** *Insert #* ☐ **Site will not enroll**	☐ External Site will rely on the CM IRB as the IRB of Record using a reliance agreement. () ☐ **Not Applicable**. Site will **not** interact or intervene with human participants or their identifiable data / identifiable biospecimens. Site is also not a primary NIH or federal grant recipient.

34.0 International Research

34.1 N/A- no international research is part of this study.

Addendum B: Waiver/Alteration of Permission/Assent/Consent

NOTE: *If requesting a waiver of parental/LAR permission because parental permission is not a reasonable requirement to protect the participants [e.g. research on neglected or abused children], contact irb@cmh.edu to discuss additional regulatory requirements.*

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent,* ***ALL*** *of the following must apply. Explain how the study meets each of the regulatory criteria below.*

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	We are requesting a Waiver of Consent at age 18 to allow data to continue to be retained in the DSDR without reconsenting participants when they turn 18. This study involves no more than minimal risk in comparing two standard anesthesia methods and collecting data from patients' medical records. Continuing to keep the data in the repository after patients turn 18 does not increase the risk of the study, as parents and patients will have been informed at the time of Permission/Assent that the data being contributed to the DSDR for use in future studies.
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	Reconsenting patients at age 18 would not be practicable for several reasons. This study only enrolls patients up to age 8. Most of these patients will not have ongoing treatment or contact with CMH for 10 years or more until they potentially turn 18, and many would likely be lost to contact. Retaining all of the data from the initial data set will be necessary to ensure usefulness of this data for any future studies.
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	Just as identifiers are necessary in the initial study to verify data accuracy and compare time points and intervals during treatment, these identifiers need to be retained in the data repository to allow this data to be useful in future studies.
The waiver/alteration will not adversely affect the rights and welfare of the participants	A Waiver of Consent at age 18 does not adversely affect the rights or welfare of participants, as their parents will have already given their permission to include this data in the repository, where it will have already been stored for 10 years or more before participants turn 18.

Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	This is not applicable to a Waiver of Consent at age 18. If any pertinent information for parents or participants were to be discovered, parents and/or participants would be informed no matter the age of participants at that time. It is unlikely that any pertinent information would be discovered though after patients turn 18, as the study will have been concluded for several years by that time.

Proposed Alteration (if applicable):

Select which required elements of permission are to be omitted.

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the participant;

☐ A description of any benefits to the participant or to others that may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

☐ A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Provide the rationale for omitting the item(s) selected:

*Addendum E: Waiver/Alteration of HIPAA Authorization***

** For 18 + reauthorization

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. Assurance that PHI will not be reused or disclosed to any other person or entity:	We are requesting a Waiver of HIPAA Authorization at age 18 to be able to continue to retain PHI. PHI will be retained in the repository to allow this data to be useful for potential future research studies involving LMA or hernia repair. PHI will only be disclosed if a future study has IRB approval to request the data from the DSDR and meets any other requirements of the DSDR for data use.
The research cannot practicably be conducted without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	Requiring reauthorization of HIPAA when patients turn 18 would be impracticable. This study only enrolls patients up to age 8. Most of these patients will not have ongoing treatment or contact with CMH for 10 years or more until they potentially turn 18, and many would likely be lost to contact.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	Retaining all the PHI from the initial data set will be necessary to ensure usefulness of this data for any future studies.

*Addendum E: Waiver/Alteration of HIPAA Authorization***

** For Pre-Screening

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: d. Plan to protect PHI from improper use and disclosure: e. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: f. Assurance that PHI will not be reused or disclosed to any other person or entity:	PHI will only be available to and accessed by IRB approved study staff. Health or research justification for keeping PHI: PHI **will** be reused, disclosed, or transferred outside of the study team: Contributing data to an existing CM repository protocol (myIRB#18020079) PHI will only be available to and accessed by IRB approved study staff.
The research cannot practicably be conducted without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	Partial Waiver of HIPAA Authorization for Recruitment only: It is necessary to access PHI prior to speaking with patients and families, to determine if patients are eligible for the study. It is not practical to obtain written HIPAA authorization for any patient that may meet the inclusion criteria as the study team will not know who may be eligible for screening.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	PHI is necessary to ascertain whether the participant meets the inclusion criteria, and all collected data is needed to meet the study aims.