A non-opioid technique for post-operative pain relief after adenoidectomy

NCT03714919

April 8, 2019

PROTOCOL TITLE:

A non-opioid technique for post-operative pain relief after adenoidectomy.

PRINCIPAL INVESTIGATOR:

Name: Arlyne Thung, MD
Department/Center: Anesthesiology & Pain Medicine
Telephone Number: 614-722-4200
Email Address: Arlyne.Thung@nationwidechildrens.org

VERSION NUMBER/DATE:

Version 2 / April 8, 2019

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
2	4/8/2019	Changing recruitment procedures	No

1.0 Study Summary

Study Title	A non-opioid technique for post-operative pain relief after adenoidectomy
Study Design	Prospective, open-label
Primary Objective	To assess analgesic efficacy of a multi-modal, non-opioid analgesic regimen for providing surgical analgesia in pediatric patients undergoing adenoidectomy.
Secondary Objective(s)	To assess recovery characteristics in the PACU and at home following surgery.
Research Intervention(s)/ Investigational Agent(s)	Dextromethorphan, Acetaminophen, Dexmedetomidine, Ketamine
IND/IDE #	138411
Study Population	Children aged 4-8 years undergoing adenoidectomy
Sample Size	10
Study Duration for individual participants	Day of surgery up to 72 hours post-op
Study Specific Abbreviations/ Definitions	PACU - post anesthesia care unit FLACC - Faces, Legs, Activity, Cry, Consolability Scale PAED - Pediatric Agitation and Emergence Delirium Scale

2.0 Objectives

2.1 To assess analgesic efficacy of a multi-modal, non-opioid analgesic regimen for providing surgical analgesia in pediatric patients undergoing adenoidectomy

2.2 To assess recovery characteristics in the PACU and at home following surgery

2.3 We hypothesize in this pilot study that a multimodal analgesic technique consisting of oral dextromethorphan, oral acetaminophen, dexmedetomidine and ketamine is an effective analgesic regimen pediatric patients undergoing adenoidectomy.

3.0 Background

3.1 Pediatric patients undergoing adenoidectomy experience post-operative pain that requires pharmacological therapy in which opioid medications are the mainstay of treatment. However opioids have potential undesirable side effects that may include itchiness, nausea, respiratory depression. In this surgical patient population, where symptoms of sleep disordered breathing and nasal obstruction may often times be present, side effects such as these are particularly undesirable and may lead to lengthened recovery or even hospital admission. Single

therapy with a non-opioid analgesic may not provide sufficient post-operative analgesia, however, using various agents with different mechanisms of action allows additive and synergistic effects. We therefore developed a non-opioid analgesic protocol that include medications which have been previously utilized for pain management in pediatric patient undergoing otolaryngology procedures consisting of pre-operative dextromethorphan and acetaminophen and intraoperative dexmedetomidine, and ketamine.

3.2 Dextromethorphan is a readily available over the counter medication used most commonly for its antitussive effect in pediatric patients with an analgesic mechanism exerted through NMDA antagonism. Preoperative use of dextromethorphan has been shown by some authors to reduce postoperative opioid requirements with Dawson et al1 showing reduced morphine consumption in pediatric adeno-tonsillectomy patients.

3.3 Acetaminophen (paracetamol) is a first-line antipyretic and analgesic for mild and moderate pain and is a mainstay treatment in pediatric patient undergoing ENT procedures due to its easy accessibility and wide use particularly in oral form. Its anti-nociceptive mechanism involves central inhibition of the cyclo-oxygenase (COX) enzyme leading to decreased production of prostaglandins, which in turn diminishes the release of excitatory transmitters involved in nociceptive transmission2,3.

3.4 Dexmedetomidine is an α2-adrenergic receptor agonist with anxiolytic, nociceptive and sedative properties with minimal respiratory depressive properties. It is commonly used for sedation in the intensive care unit as well as procedural sedation and has shown to be effective in pediatric patients undergoing ENT procedures due to its desirable effect of providing effective analgesia and reducing emergence agitation and postoperative opioid requirements4-6.

3.5 Ketamine is a phencyclidine derivative with well-known sedative and analgesic properties modulated through NMDA antagonism. Several studies have reported Ketamine's role as an effective analgesic adjuvant in pediatric patients undergoing tonsillectomy when combined with opioids, paracetamol and dexmedetomidine in low doses7-9 resulting in lower postoperative pain scores and opioid consumption. In a meta-analysis looking at the efficacy of Ketamine in improving pain after pediatric tonsillectomy, Cho et al concluded that pre-emptive administration of ketamine was associated with decreased surgical pain and analgesic consumption with a low incidence of adverse effects such as nausea/vomiting, sedation or hallucinations10.

3.6 Adenoidectomy is one of the most common surgeries performed in the pediatric population in the United States. The most frequent indications for surgery are airway obstruction leading to obstructive breathing and obstructive sleep apnea, and chronic or recurrent infection

of the sinuses, ear canal or pharynx. Adenoidectomy is often performed in conjunction with tonsillectomy, however is also frequently performed alone. Whilst adenoidectomy is frequently performed in the ambulatory setting, comorbid medical conditions, and risk of post-operative respiratory depression may be among reasons for elective hospital admission.

3.7 The authors hope that this pilot study will illustrate the efficacy and viability of a multimodal, completely non-opioid analgesic technique for operative pain management after adenoidectomy in the pediatric population. Such a technique could be useful not only in pediatric patient populations including those at risk of postoperative respiratory compromise in whom the use of opioids analgesics for perioperative pain managements is a concern but could meaningfully contribute to understanding of pediatric pain management in a geographical area where the opioid crisis has reached critical proportions. Study results will be presented at national meetings and submitted for journal publication. In addition, the current study will lay the groundwork for future studies which would investigate this non-opioid analgesic technique for use in tonsillectomy surgery.

4.0 Study Endpoints

4.1 The primary outcome will be need for rescue opioid analgesia in the PACU. Other variables such as time to extubation in the PACU, time to first analgesic delivery, pain scores, number and total dose of opioids given, presence of sedation, nausea/vomiting, hallucinations, duration of oxygen requirement in PACU, and total PACU time will be recorded during the duration of the patient's PACU stay.

5.0 Study Intervention/Investigational Agent

5.1 Description: Preoperative oral dextromethorphan 1mg/kg, preoperative oral acetaminophen 15mg/kg, intraoperative intravenous dexmedetomidine 0.5 mcg/kg, intraoperative intravenous ketamine 0.5mg/kg.

5.2 Drug/Device Handling: All study medications will be controlled by Investigational Drug Services following the Research Pharmacy SOP for the Control of Investigational Drugs.

5.3 Dr. Arlyne Thung is the holder of the IND. All drugs will be administered one time in doses that have been previously reported to be in recommended dosing range. In reporting adverse events we will follow the final regulations issued by the Food and Drug addressing the safety reporting requirements for investigational new drug applications (INDs) found in 21 CFR part 312 and for bioavailability and bioequivalence studies found in 21 CFR part 320. “Safety Reporting Requirements for INDs and BA/BE Studies”.

5.4 The classification for adverse events to be used is the following:

Mild adverse event; did not require treatment

Moderate adverse event; resolved with treatment

Severe adverse event; inability to carry on normal activities; required professional medical attention

Life-threatening or permanently disabling adverse event

Fatal adverse event

In this grading system, severity is not equivalent to seriousness. The definitions to be employed will follow the final regulations issued by the FDA in September 2010 "Safety Reporting Requirements for INDs and BA/BE Studies", and described in section 7.0 of this protocol.

5.5 Dose limiting toxicity (DLT) is defined as any adverse event that is possibly, probably, or definitely related to the study agent. This would include any grade 3 according to the classification given above. Study enrollment will be halted by the investigators when any subject experiences a Grade 3, or higher adverse event toxicity that is possibly, probably, or definitely related to the study drug. The event will then be reviewed by the physician responsible for review and evaluation of information relevant to the safety of the drug.

The PI will fulfill the reporting responsibilities under 21 CFR 312.32(c), to notify the FDA in an IND safety report of potentially serious risks, as soon as possible, but no later than 15 calendar days after the investigator receives the safety information and determines that the information qualifies for reporting. The investigator will confer with the, IRB and FDA before enrollment.

5.6 The Principal Investigator (PI) will monitor safety data on a continual basis throughout the trial. The PI can recommend early termination of the trial for reasons of safety. Study enrollment will be halted by the investigators when any subject experiences a Grade 3, or higher adverse event toxicity that is possibly, probably, or definitely related to the study drug. This will include any patient death, important clinical laboratory finding, or any severe local complication related to the study agent. If after review by the IRB and FDA, the decision is made to continue, the study will proceed.

5.7 Definition of an Adverse Event

As stated above this protocol will follow the final regulations issued by the Food and Drug Administration addressing the safety reporting requirements for investigational new drug applications (INDs) found in 21 CFR part 312.

Adverse Event (AE): Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Adverse events will be graded by the investigator accordingly: 1 = mild, 2 = moderate, 3 = severe, 4 = life threatening or debilitating, and 5 = fatal.

Association or relatedness to the study agent, study procedures and the subject's preexisting disease will be graded as follows: 5 = unrelated, 4 = unlikely, 3 = possibly, 2 = probably, and 1 = definitely related.

Adverse reaction: An adverse reaction means any adverse event caused by a drug. Adverse reactions are a subset of all suspected adverse reactions for which there is reason to conclude that the drug caused the event.

Suspected adverse reaction (21 CFR 312.32(a)) Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, 'reasonable possibility' means there is evidence to suggest a causal relationship between the drug and the adverse event. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.

5.8 Serious adverse event (SAE)

An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

To reiterate, an SAE is an event in categories 3, 4, and 5. Category 3 Severe adverse event; inability to carry on normal activities; required professional medical attention Category 4 Life-threatening or permanently disabling adverse event Category 5 Fatal adverse event.

5.9 Life-threatening (21 CFR 312.32(a))

An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death. The PI will

fulfill the reporting responsibilities to FDA on behalf of Nationwide Children's Hospital, by completing a Form FDA 3500 either online, by fax (1-800-FDA-0178) or calling the FDA at 1-800-FDA-1088.

5.10 Obligations of the Investigator

The Principal Investigator will submit a voluntary Form FDA 3500 by one of the methods mentioned above for any serious adverse event that is both unexpected and associated with the use of the study drug(s).

The Principal Investigator will adhere to any other serious adverse event reporting requirements in accordance with federal regulations, state laws, and the local institutional policies and procedures, as applicable.

The Principal Investigator will be responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

6.0 Procedures Involved*

6.1 The anesthesia research staff will review the upcoming surgery schedules for eligible subjects. They will then mail the family the study information sheet and a copy of the consent form. On the day of surgery a member of the investigative team will approach eligible families to: answer any questions regarding the study, discuss the study in further detail, and obtain consent from parents/guardians who agree to enroll their child in the study.

6.2 On the day of surgery, if the parent(s)/legal guardian(s) state they are not interested in enrolling their child, they will be thanked for their time and no further study discussion will occur. At any time and for any reason, parent/guardians who have initially enrolled their child in the study, may have their child withdrawn from the study if the parents/guardians are uncomfortable with their child's participation. All efforts will be made to recruit patients from the ENT specialists who are listed as co-investigators, however the investigative team would like to recruit patients from all ENT specialists who meet eligibility criteria and who have received the information sheet and consent prior to the day of surgery.

6.3 Once enrolled, subjects will be administered a standardized anesthetic and pain regimen which will consist of: Anesthetic regimen:

a. Pre-medication with oral midazolam (0.3 mg/kg to maximum dose of 20 mg) given 15-20 minutes before induction

b. Inhalation induction with sevoflurane and a mixture of N20/02

c. Propofol 1-1.5 mg/kg to facilitate endotracheal intubation

d. Maintenance anesthesia with isoflurane with a mixture of air and oxygen, titrated to a BIS of < 60

e. Ondansetron (0.15 mg/kg, maximum dose of 4 mg) and dexamethasone (0.25 mg/kg, maximum dose of 20 mg) for postoperative nausea prophylaxis.

f. Intravenous fluids (Lactated Ringers or Normal Saline) 20-40 mL/kg

6.4 Pain regimen:

Preoperative oral dextromethorphan 1 mg/kg

Preoperative oral acetaminophen 15 mg/kg

Intraoperative intravenous dexmedetomidine 0.5 μg/kg

Intraoperative intravenous ketamine 0.5mg/kg

6.5 Following surgery and tracheal extubation, baseline vitals will be obtained and pain scores will be assessed in the post anesthesia care unit (PACU) via FLACC (Faces, Legs, Activity, Cry, Consolability Scale).The presence of emergence delirium will be assessed via PAED (Pediatric Agitation and Emergence Delirium Scale). Those subjects whose pain score is assessed at < 5 will receive standard postoperative care and no analgesics. Patients with an assessed pain score > 4 will receive 0.5 μg/kg fentanyl every 10 minutes as needed. The primary outcome will be need for rescue opioid analgesia in the PACU. Other variables such as time to extubation in the PACU, time to first analgesic delivery, pain scores, number and total dose of opioids given, presence of sedation, nausea/vomiting, hallucinations, duration of oxygen requirement in PACU, and total PACU time will be recorded during the duration of the patient's PACU stay. Subjects will be discharged home from the PACU once standard discharge criteria have been met.

6.6 Patients will be discharged from the hospital with standard instructions to use appropriate weight based doses of oral acetaminophen q6hrs for pain and ibuprofen for breakthrough pain. They will be given a pain diary to record pain scores and analgesic use from hospital discharge to 72 post-operative hours. A member of the investigative team will contact the patients' guardian by telephone to obtain this information as well as answer any questions regarding post-anesthetic recovery.

7.0 Data and Specimen Banking*

7.1 No data or specimens will be banked for future use.

8.0 Sharing of Results with Subjects*

8.1 Study results will not be shared with subjects or others.

9.0 Study Timelines*

9.1 An individual study subject's participation in the study should last approximately 48 hours total.

9.2 All study subjects should be enrolled within 2 years of study start.

9.3 The study should be completed within 3 years of study start.

10.0 Inclusion and Exclusion Criteria*

10.1 Inclusion:

Male or female patients aged 3-8 years undergoing adenoidectomy +/- bilateral myringotomy tube placement

Subjects who have a parent/guardian who are compliant with routine medical care, capable of subjective evaluation and able to read, understand and sign the informed consent in accordance with HIC regulations.

10.2 Exclusion:

An American Society of Anesthesiologists Physical Status ≥ 4 (severe disease that is life threatening);

A known hypersensitivity or allergy to any of the study medications;

A history of chronic opioid use prior to surgery;

Coexisting renal or hepatic disease;

Morbid obesity (BMI% ≥ 99).

10.3 We are including children, and will not include:

- Adults unable to consent
- Pregnant women
- Prisoners

11.0 Vulnerable Populations*

11.1 The research involves greater than Minimal Risk to subjects, but presents the prospect of direct benefit to the individual subjects. Subjects have the potential benefit of needing less opioid pain medication following surgery. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, which include opioids administered post-operatively.

11.2 Because of the prospect of direct benefit, permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. .

12.0 Local Number of Subjects

12.1 We plan to enroll 10 study subjects.

13.0 Recruitment Methods

13.1 The anesthesia research staff will review the upcoming surgery schedules for eligible subjects. They will then mail the family the study

information sheet and a copy of the consent form. On the day of surgery a member of the investigative team will approach eligible families to: answer any questions regarding the study, discuss the study in further detail, and obtain consent from parents/guardians who agree to enroll their child in the study.

13.2 Subjects will not be paid.

14.0 Withdrawal of Subjects*

N/A

15.0 Risks to Subjects*

15.1 The common side effects associated with acetaminophen are nausea, vomiting, constipation, itching, agitation, and difficulty breathing which may occur in approximately 5% of patients.

Occasional or rare side effects are low blood count; fast heartbeat; abdominal pain; diarrhea; pain, swelling, abnormal lab values; muscle spasm; headache; difficulty sleeping; frequent peeing; high or low blood pressure. This may occur in approximately 1% of patients.

15.2 The common side effects associated with dextromethorphan are dizziness, drowsiness, restlessness, nausea, vomiting and stomach pain.

Occasional or rare side effects are difficulty breathing, fast heartbeat or hallucinating (seeing things or hearing voices that do not exist).

15.3 The common side effects associated with ketamine are fast heartbeat, high blood pressure, confusion and hallucinations.

Occasional or rare side effects are vomiting, abnormal heart rhythm, difficulty breathing, double vision and increased muscle tone.

15.4 Common side effects of dexmedetomidine are low or high blood pressure, nausea, slow heart rate, dry mouth and prolonged sleepiness or sedation.

16.0 Potential Benefits to Subjects*

16.1 Subjects have the potential benefit of needing less opioid pain medication following surgery.

17.0 Data Management* and Confidentiality

17.1 All data and observations will be documented by source documentation. The PI will be responsible for reviewing and evaluation of information relevant to the safety of the drug.

17.2 This is a pilot study examining the feasibility of a non-opioid technique for pediatric patients undergoing adenoidectomy. 10 volunteer patients were the agreed upon number between the Departments of Anesthesiology and Otolaryngology.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 The study will be monitored in compliance with the relevant parts of 21 CFR and according to the ICH GCP Guidelines. The procedures outlined in the protocol and case report forms will be carefully reviewed by the PI and staff prior to study initiation to ensure appropriate interpretation and implementation. No deviations from the protocol shall be made except in emergency situations where alternative treatment is necessary for the protection, proper care and wellbeing of subjects.

18.2 All subjects will be clinically monitored as it pertains to routine anesthetic care during the surgical procedure. This includes the use of standard ASA (American Society of Anesthesiology) monitors which measure ventilation (end tidal C02, inspired anesthetic gases), oxygenation (pulse oximetry), temperature and circulation (heart rate, blood pressure and EKG assessments every 5 minutes). In addition, all subjects will have BIS (Bispectral Index) monitoring used to assess the depth anesthetic as well as guide titration of anesthetic agents. Following completion of their surgical procedure all subjects will be monitored in the post anesthesia care unit as per routine in which vitals, pain scores and recovery variables (i.e. presence of emergence delirium as assessed by the Pediatric Agitation and Emergence Delerium scale, nausea/vomiting, hallucinations) will be assessed by the nursing team. Duration of PACU time will be recorded once subjects have demonstrated discharge criteria.

18.3 Amendments will be submitted to the Nationwide Children's Hospital IRB for their review and approval prior to implementation. When an amendment to a protocol substantially alters the study design or increases potential risk to the study subject, the Informed Consent Form will be revised and if applicable, subject's consent to continue participation will again be obtained.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

20.0 Compensation for Research-Related Injury

20.1 None

21.0 Economic Burden to Subjects

21.1 None

22.0 Consent Process

22.1 The consent process will begin in the ENT clinic and continue in the preoperative surgery unit on the day of surgery, by PI, Sub-Investigators, Study Coordinators, and/or trained research staff.

22.2 The study will be thoroughly explained to the patient and their family. There will be ample time allotted for questions and answers. An explanation of voluntary participation will take place, and the family will be asked if they are interested in participating in the study. If the patient and their parent(s), or legal guardian agrees to participate they will be asked to sign consent and assent forms. The patient will then be enrolled in the study with the understanding that they can elect to stop the study and be withdrawn from the study at any time.

23.0 Process to Document Consent in Writing

23.1 We will be following "SOP: Written Documentation of Consent (HRP-091)."

24.0 Setting

24.1 Potential subjects will be identified and recruited from the ENT clinic. Research procedures will be performed in the Surgery Unit, OR, and PACU.

25.0 Resources Available

25.1 The department of Anesthesiology and Pain Medicine has 2 research coordinators and 2 research associates that will be enrolling subjects for this study. All study staff will be trained on the study procedures.

26.0 Multi-Site Research*

N/A

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

- ☒ Name
- ☒ Complete Address
- ☒ Telephone or Fax Number
- ☐ Social Security Number (do not check if only used for ClinCard)
- ☒ Dates (treatment dates, birth date, date of death)
- ☐ Email address , IP address or url
- ☒ Medical Record Number or other account number
- ☐ Health Plan Beneficiary Identification Number
- ☐ Full face photographic images and/or any comparable images (x-rays)
- ☐ Account Numbers
- ☐ Certificate/License Numbers

☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☒ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)
☐ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)
☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)
☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)
☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

***Find the HIPAA forms in the IRB Website Library, Templates.**

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained? Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

4.0 Describe any plans to code identifiable information collected about each participant. None

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

☒ **Research records will be stored in a locked cabinet in a secure location**
☒ **Research records will be stored in a password-protected computer file**
☐ **The list linking the assigned code number to the individual subject will be maintained separately from the other research data**
☒ **Only certified research personnel will be given access to identifiable subject information**

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of

individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)
Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

- ☒ Demographics (age, gender, educational level)
- ☐ Diagnosis
- ☐ Laboratory reports
- ☐ Radiology reports
- ☐ Discharge summaries
- ☒ Procedures/Treatments received
- ☒ Dates related to course of treatment (admission, surgery, discharge)
- ☐ Billing information
- ☒ Names of drugs and/or devices used as part of treatment
- ☐ Location of treatment
- ☐ Name of treatment provider
- ☐ Surgical reports
- ☒ Other information related to course of treatment
- ☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to meet the objectives of the study and to analyze the data.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No