Protocol Document:

Nonopioid versus opioid outpatient pain management following surgical fixation of Gartland Type III supracondylar humerus fracture in children: a prospective, randomized trial

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PROTOCOL TITLE:

Nonopioid versus opioid outpatient pain management following surgical fixation of Gartland Type III supracondylar humerus fractures in children: A prospective, randomized study

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/8/2019	IRB requested changes	yes
2	6/13/2019	Adding advertisement for CMH staff	no
3	9.16.21	Adding KUMC Resident to study. Tanner Campbell, MD	yes
4	10.25.22	Adding Dr. Jonathan Warren and George Thomas to the study Updating protocol to add Twilio for contacting families	yes
5	12.16.2024	Adding Dr. Caleb Grote MD, PhD as Primary Investigator	No

Table of Contents

1.0 Study Summary

Study Title	Nonopioid versus opioid outpatient pain management following surgical treatment of Gartland type III supracondylar humerus fractures in children: A prospective, randomized study
Study Design	Prospective, two-arm, parallel-group, randomized study conducted at a single center
Primary Objective	To determine if nonopioid analgesic regimens are non-inferior to opioid analgesic regimens in managing postoperative pain in the outpatient period following surgical treatment of Gartland type III supracondylar humerus fractures in children.
Secondary Objective(s)	To describe outpatient pain management following surgical treatment of Gartland type III supracondylar humerus fractures in children.
Research Intervention(s)/ Investigational Agent(s)	Control Group (opioid group): Hydrocodone/acetaminophen 0.15mg/kg PO q6 hours PRN with ibuprofen 10mg/kg PO q6 hours PRN Experimental Group (nonopioid group): Acetaminophen 15mg/kg PO q6 hours with ibuprofen 10mg/kg PO q6 hours
IND/IDE #	N/A
Study Population	Patients 48-119 months of age presenting to Children's Mercy Hospital Adele Hall campus for surgical treatment of a Gartland type III supracondylar humerus fracture.
Sample Size	160 (up to 300 to be pre-screened)
Study Duration for Individual Participants	Study participation starts at the time of presentation at Children's Mercy Hospital Adele Hall campus and ends at the third follow-up visit. Study duration for individual participants will be approximately 6-12 weeks.
Study Specific Abbreviations/ Definitions	SCHF: supracondylar humerus fracture O: Opioid group NO: Nonopioid group

2.0 Objectives

Our primary objective is to determine if nonopioid analgesic regimens are non-inferior to opioid analgesic regimens in the management of post-operative pain in the outpatient period following surgical fixation of Gartland type III SCHFs in children.

We hypothesize that there is no difference in daily pain levels for nonopioid analgesic regimens compared to opioid analgesic regimens in management of post-operative pain in the outpatient period following surgical fixation of Gartland type III supracondylar humerus fracture in children.

3.0 Background

Pain is variably managed in pediatric populations, particularly in the postoperative outpatient setting.[1,3,5,6] The lack of data describing and supporting the safety and efficacy of the use of analgesic drugs in children is a major contributor to this problem. Postoperative prescription opioids have been associated with high rates of morbidity and mortality in children and identified as a pathway to future opioid abuse.[7-9] With increasing public awareness regarding these issues surrounding opioid use and no evidence to support superior treatment outcomes in children with the use of opioids, there is a pressing need for data to guide healthcare providers in choosing analgesic drugs to treat postoperative pain in pediatric patients.[5]

Prior studies have evaluated the use of nonopioid versus opioid analgesic drugs in the outpatient setting following pediatric ambulatory surgery.[1,3,5] These studies found nonopioid analgesics, such as acetaminophen and ibuprofen, to be as equally effective as opioid analgesics, including morphine, codeine and oxycodone. Further, the use of nonopioid analgesics was associated with significantly fewer side effects.[1,3,5] These findings imply that nonopioid analgesics may be a superior initial therapy following ambulatory surgery.

However, no study has evaluated the use of nonopioid versus opioid analgesic regimens in the outpatient setting following surgical fixation of supracondylar humerus fractures (SCHFs). SCHFs are the second most common fracture in children, often requiring urgent surgical intervention.[10] Despite their frequency, there is no standard for postoperative outpatient pain management in the treatment of these injuries.

Almost all SCHFs can be described according to the Gartland classification. The Gartland classification delineates three types of SCHFs. Gartland type I fractures are nondisplaced and do not require surgical intervention, while Gartland type II fractures are angulated, but maintain an intact posterior cortex. These may or may not require surgical intervention. However, Gartland type III fractures are completely displaced with no posterior cortical contact and require surgical intervention with either closed reduction and percutaneous pinning (CRPP) or open reduction with percutaneous pinning (ORPP). This study will look at only Gartland type III SCHFs because they necessitate surgical intervention, most commonly CRPP.[10, 12]

This study aims to determine the efficacy of nonopioid versus opioid analgesic regimens following surgical fixation of Gartland Type III SCHFs to assist in the development of a standard outpatient pain management regimen in the treatment of these injuries.

4.0 Study Endpoints

The primary outcome will be subject reported pain level, which will be measured using the Wong-Baker Faces Pain Scale.[14] The subject reported pain level will be measured at the time of discharge (i.e., baseline measure) and at the relative same time each day on postoperative days 1-5 (i.e., five follow-up measures). Thus, subject s may have up to a total of six pain level measurements.

Secondary outcomes include:

1) Parent satisfaction with (subject) child's pain control measured using a Likert Scale at the time of discharge and at the relative same time each day on postoperative days 1-5
2) Daily use of opioid or nonopioid medicine on postoperative days 1-5
3) Number of days of medication use
4) Side effects experienced
5) Use of medication(s) other than those indicated by their physician to control pain
6) Number of calls to a healthcare provider for breakthrough pain rescue
7) Number of visits to a healthcare provider for breakthrough pain rescue
8) Overall control of patient's pain in postoperative days 1-5
9) Overall parent satisfaction with patient's pain control in postoperative days 1-5

Secondary outcomes 3-9 will be measured using a standard questionnaire, which will take approximately five minutes to complete by a parent at the first follow-up visit.

5.0 Study Intervention/Investigational Agent

Acetaminophen is an analgesic and antipyretic approved by the United States Food and Drug Administration (FDA) for the treatment of postoperative pain in children. It is approved for over-the-counter use in the form of tablets, chewable tablets, gel tabs, capsules and liquid.

Hydrocodone is an opioid analgesic approved by the United States FDA for the treatment of postoperative pain in children. It is approved for prescription use in the form of tablets, capsules and liquid. Hydrocodone is often prescribed with acetaminophen as a combination medication (Lortab).

Patients will be randomized into one of two study groups using the REDCap Randomization Module. The Opioid (O) Group will receive a five day prescription for oral hydrocodone/acetaminophen at a dose of 0.15mg/kg to be taken every six hours as needed in addition to oral ibuprofen at a dose of 10mg/kg to be taken every six hours as needed. The Nonopioid (NO) Group will receive oral acetaminophen at a dose of 15mg/kg to be taken with oral ibuprofen 10mg/kg every six hours. At parental discretion, patients in both groups will self-transition to taking only oral ibuprofen at a dose of 10mg/kg every six hours as needed.

Subjects will go home with their assigned medication available for them from the CMH Outpatient pharmacy. At discharge, both groups will follow the standard of care from the inpatient unit to obtain their pain medication for home use. If acetaminophen and/or ibuprofen are readily available at home, families may decline purchasing from the CMH outpatient pharmacy.

6.0 Procedures Involved

Study Design:
This is a prospective, two-arm, parallel-group, non-inferiority, randomized study including subject 48-119 months of age presenting to Children's Mercy Hospital for surgical correction of Gartland type III SCHFs. Only subject meeting the inclusion/exclusion criteria will be eligible for this study. All eligible subject will be randomized to receive a postoperative outpatient pain management regimen that includes opioid analgesics (O group) or a postoperative outpatient pain management regimen that does not include opioid analgesics (NO group).

Study Overview/Methods:
All eligible patients meeting the inclusion criteria will be admitted under inpatient status until the time of surgery. Subject will undergo operative treatment of their displaced supracondylar humerus fracture within 18 hours of injury. Subjects will receive standard perioperative anesthesia. Surgeons involved in the study will operate and treat each fracture with the reduction and fixation technique they deem appropriate for the individual subject. Subjects will receive ketorolac 0.5mg/kg IV single-dose up to 30mg in the operating room at the completion of the procedure. Subjects will be immobilized in either a splint or bivalve fiberglass cast. Subjects will be treated in the post-anesthesia care unit (PACU) with standard pain management. Subjects will be treated in the observation setting with standard pain management and go home within 24 hours of surgery. Patients not admitted pre-op, not admitted post-op or staying longer than 24 hours after surgery will be excluded from the study.

Parental consent for patient participation in this study will be obtained by an investigator prior to discharge from the hospital. Subjects will then be randomized to receive a postoperative pain management regimen that includes opioid analgesics or a postoperative pain management regimen that does not include opioid analgesics. The randomization will be performed by an investigator using a random-number generator (REDCap Randomization Module). Subjects assigned to the O group will go home with a filled opioid prescription. Subjects assigned to the O or NO group without acetaminophen and/or ibuprofen are readily available at home, will go home with the needed medications. If a subject assigned to the NO group calls and needs to be switched to the O group, that will be discussed with the attending surgeon and, if approved, that subject's status will be changed.

Measured Outcomes:
Subject's pain will be assessed in the outpatient period using the Wong-Baker Faces Pain Rating Scale. Subject's pain scores will be recorded at the time of discharge and at

approximately the same time each day for postoperative days 1-5. Subjects will rate their pain at the time of the survey.

Parent satisfaction with their child's pain control will be assessed using a Likert Scale, 0-10 scale. Parent satisfaction scores will be recorded at the time of discharge and at the same time each day for postoperative days 1-5. Parents will rate their satisfaction with their child's pain control at the time of the survey.

The use of opioid or nonopioid medications will be reported at the same time each day for postoperative days 1-5. Parents will report if their child took their assigned medications in the past 24 hours at the time of the survey.

The patient pain score and parent satisfaction score will be recorded using a three-question survey administered by the CMH-REDCap database. A unique link will be sent to a parental email address for each survey through CMH-REDCap automated invitations. A reminder email will be sent six hours after the first email. Surveys will expire 36 hours after the first invitation to each link was sent. We will be using Twilio REDCap texting as means of survey distribution in addition to email.

All subjects will be scheduled to return to the CMH orthopedic clinic for three follow-up visits at approximately two, four and eight weeks post-op. These clinic visits are part of the standard practice at CMH. At 10 days post-op, we will record the days of medication use and the number of days to return to normal activity. We will Side effects experienced, used of medication(s) other than those indicated by their physician for pain control, number of call-ins for breakthrough pain rescue, number of unplanned visits to a healthcare provider for breakthrough pain rescue, overall control of patient pain and overall parent satisfaction with their patient pain control in postoperative days 1-5 will be assessed using a questionnaire completed by a parent. Standard of care X-ray images and physical exam will be used throughout follow-up visits to assess for complications.

7.0 Data and Specimen Banking - N/A

8.0 Genetic Analysis Information - N/A

9.0 Sharing of Results with Subjects- NA

10.0 Study Timelines

Each subject will participate in the study for approximately two months from the date of injury. This time period includes the initial presentation for injury evaluation, surgical treatment and all follow-up visits. Data will be collected from each encounter.

Given the volume of Gartland type III SCHFs that present yearly to CM-Adele Hall Campus, it is expected all study subjects will be enrolled within 18 months from the start date of this study. It will take approximately two years from the start date for investigators to complete this study.

11.0 Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients presenting to Children's Mercy Hospital
- Patients 48-119 months of age
- Closed and completely displaced Gartland type III SCHFs (ICD-10 codes: S42.411A, S42.412A and S42.413A)

Exclusion Criteria:

- Patients younger than 48 months of age or older than 120 months of age
- Nondisplaced SCHFs (ICD-10): S42.414-, S42.415- and S42.416-)
- Open and completely displaced Gartland type III SCHFs (ICD-10: S42.411B, S42.412B and S42.413B)
- Injury requiring open reduction and/or vascular injury requiring treatment
- Patients presenting with additional injuries
- Patients with known allergy to medications used in this study
- Patients receiving regular treatment with opioids or NSAIDs
- Patients with underlying medical issues affecting cognitive status
- Patients with hepatic, gastrointestinal, renal or hematologic disease/disorders
- Children that are wards of the state, prisoners or of CM employees
- Non-English speaking families
- Patients not admitted before and after surgery
- Fractures not surgically treated within 18 hours of injury
- Use of local anesthetic at surgical site

12.0 Vulnerable Populations

This study involves no more than minimal risk to the children presented to the intervention. The interventional drugs used in this study will be prescribed as approved by the United States FDA for the treatment of postoperative pain in children. The imaging, procedures, medications, clinic visits and any other medical care outlined in this protocol are all part of the usual care provided to the patient.

Permission will be attained from a biological parent. After a parent has given permission for their child to participate in the study, assent will be attained from children 7 years of age and older per CMH policy.

13.0 Local Number of Subjects

According to the CM orthopedic trauma registry, at CMH, approximately 320 children with SCHFs present annually. Of those 320 SCHFs, approximately 150 (47%) are Gartland type III fractures.

A minimum of 160 subjects will be accrued locally, 80 for each study arm. It is anticipated 20% of subjects presenting annually will be ineligible for this study, miss enrollment or decline enrollment. It is further anticipated 20% of enrolled subjects will be lost to follow-up. Therefore, it is expected that up to 300 patients may need to be

screened in order to acquire the necessary number of participants who meet the inclusion and exclusion criteria. It will take an estimated 20 months to enroll 160 total subjects.

If more than 300 subjects need to be screened or more than 160 eligible subjects are identified in less than 20 months, an amendment will be submitted to the IRB to increase the number of subjects prior to the collection of any data beyond the originally approved number. Evaluating a larger group of patients may allow for more statistically significant conclusions to be drawn regarding the efficacy of nonopioid analgesic regimens compared to opioid analgesic regimens in the treatment of postoperative pain in children following surgical correction of Gartland type III SCHFs.

14.0 Screening and Recruitment Methods

All staff orthopedic surgeons at Children's Mercy Hospital and rotating residents will be informed of the study. Any child presenting to or referred to CMH for surgical treatment of a Gartland type III SCHF will be screened for eligibility by the orthopedic resident and/or surgeon involved in their care. Upon identifying a child meeting all inclusion and exclusion criteria, the resident and/or surgeon will notify a study team member of an eligible study patient and the date/time of the patient's surgery. One of the study team members will discuss the study with the patient and family for the purpose of obtaining consent prior to discharge.

Minimum PHI will be recorded prior to obtaining informed consent. Minimum PHI on non-participants will be recorded until the completion of enrollment in order to avoid duplicate enrollment and to track where patients become ineligible for the study or why they chose not to participate in the study. We are requesting partial Waiver of HIPAA authorization of recruitment purposes only.

15.0 Withdrawal of Subjects

Subjects will be withdrawn from the research without their consent if they have an allergic reaction to any one of the study medications, suffer any major adverse effect from a medication or procedure or develop a complicated case requiring unusual or extended treatment.

The study will undergo orderly termination if it is associated with unexpected serious harm to the subjects.

Data collected from subjects up until the time of voluntarily or involuntarily withdrawal from the research will be retained unless deletion is requested by a parent.

16.0 Risks to Subjects

This study involves no more than minimal risk to the children presented to the intervention. Risks may include adverse effects related to the FDA approved study drugs.
It is possible to have an allergic reaction to any of the study drugs. Allergic reactions usually happen right away after taking the medicine by mouth and symptoms include hives, swelling of the throat, and trouble breathing. These reactions are rare. These risks

are no more than minimal as the interventional drugs used in this study will be prescribed as approved by the United States FDA for the treatment of postoperative pain in children. The medications, imaging, procedures, clinic visits and any other medical care outlined in this protocol are all part of the usual care provided to the patient.

There is a slight risk of loss of confidentiality. Subjects' confidentiality will be protected to the greatest extent possible. Each subject's confidential medical information will be maintained in the medical record as well as in a special study record that has the data collection sheet and a copy of this permission/assent form. We will keep personal identifiers separate from the study data. The study record will be locked and maintained in the research coordinator's office.

There also is a risk to confidentiality when using the internet. By providing an email address, the study team may communicate with the subject regarding survey links, survey reminders, appointment reminders and any other non-clinical, study related communication. We will be using Twilio REDCap texting as means of survey distribution in addition to email

- Corresponding through email or text is not a secure method of sending information and others may be able to access the information sent.
- The information may not be secure if storing or viewing the permission/assent document on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena.
- Information that is sent through e-mail or text may be kept on the Hospital's or subjects' service provider's (Google, Yahoo, MSN, etc) network servers. Unlike paper copies, e-copies delivered directly to the subjects' PED may not be able to be permanently removed.

This is a prospective randomized controlled trail using secured data from patient CM-Cerner accounts. There is a minimal risk of a breach in confidentiality of the PHI of subjects involved with this study. All data will be secured in a password protected CM-REDCap database available only to approved study members. If there is a breach of confidentiality, the study coordinator will submit a reportable event to the Pediatric Institutional Review Board (IRB) at The Children's Mercy Hospital and Clinics and work with the study team to resolve the situation.

17.0 Potential Benefits to Subjects

This study may not directly benefit individual subjects taking part in the research.

18.0 Investigator Assessment of Risk/Benefits Ratio: **(IRB makes the final determination)**

Select as applicable:	**Pediatric Risk Category:**	
X	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)

19.0 Data Management and Confidentiality

This study was powered to detect a between-group difference in the primary outcome of patient reported pain level. A difference in pain intensity of one face on the Faces Pain Scale (0-5) has been shown to be a minimal clinically important difference.[5] Referencing the numbers in the Poonai et al article, a sample size estimate of 80 and 80 per group (160 total) achieves 80% power to detect non-inferiority using a two-sided, Mann-Whitney test assuming that the actual distribution is uniform; margin of non-inferiority is 1.0. The true difference between the means is assumed to be 0.0. The significance level (alpha) of the test is 0.05. The data are drawn from populations with standard deviations of 2.0 and 2.0.

This is a randomized study of 160 subjects 48-119 months of age who present to CMH for surgical treatment of Gartland type III SCHFs. Subjects will be randomly allocated to O group or NO group and followed for up to 12 weeks after surgery. Outcome measures include daily patient pain level, daily parent satisfaction, daily use of medications, total number of days of medication use, side effects experienced, list of all medications used, number of calls/visits to healthcare provider for breakthrough pain rescue, overall pain control and over parent satisfaction with pain control. Additional data collected at study completion includes patient demographics, occurrence of complications, and functional and assessment of surgical treatment.

Patients will be randomly allocated to the O group (n=80) and NO group (n=80). The primary outcome will evaluate differences in patient reported pain levels between these two groups from baseline up to and including postoperative day 5. Secondary outcomes will evaluate differences between these two groups from baseline up to and including postoperative day 5 and for patients who return to the CMH orthopedic clinic for three follow-up visits at approximately two, four and eight weeks post-op.

Mann-Whitney Wilcoxon (two-sided) tests will be used to compare patient pain levels between patients with opioid regimen compared to patients with nonopioid regimen for each of the five postoperative days. Regression techniques will also be used to compare the slopes between these patients over the five postoperative days. Data will be examined to determine if demographics and characteristics are related to patients changing treatment regimens and/or leaving the study. Descriptive statistics will be conducted to describe the characteristics of the sample. P-values (two-sided) <0.05 regarded as statistically significant. Data analysis will be conducted using Stata 14.2 software (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

PHI will be collected and stored in the CMH-REDCap database including patient first name, last name, date of birth, MRN, parent first name, parent last name, parent email address, and dates and times of service.

Subject information recorded at presentation will include age, gender, drug allergies, current medications, cognitive impairment, comorbidities, laterality of injury, mechanism of injury, extension or flexion injury, direction of displacement, open injury, additional injury, vascular injury and neuropraxia. Surgical information to be collected will include

surgeon, reduction technique, number of pins placed, location of pins placed, use of local anesthetic, time between presentation and injury, duration of surgery, and number of doses of opioid/nonopioid medication received postoperatively prior to discharge. Further information to be collected will include the time between discharge and each follow-up visit.

Data will be collected and stored in the password protected CM-REDCap database. No data will be available or shared with any other entity or individual than the listed study personnel. Only the data points of interest will be available for analysis. As soon as all data points are entered into the research database, a master linking list will be maintained that links each subject's medical record number with their study number. Subjects not meeting the more specific inclusion/exclusion criteria will be removed from the list and no data will be recorded. Security measures include the storage of all data on a password protected computer in a restricted assess departmental folder limited to only listed study personnel.

Per the guidelines, data will be store for the longer of the following: (1) Five years from the date of publication, or if not published (2) Five years from completion of all reporting requirements, or (3) At least three years after the final report is completed and accepted by the IRB.

A Certificate of Confidentiality has not been issued for this study.

Study data will be evaluated by the PI after every 30 subjects are enrolled and throughout the duration of the study for Quality Control.

20.0 Provisions to Monitor the Data to Ensure the Safety of Subjects - N/A

21.0 Provisions to Protect the Privacy Interests of Subjects

PHI to be accessed and/or recorded for this research study will include: last name, first name, date of birth, medical record number, and date(s) of service. PHI will be stored in the password protected CMH-REDCap database. No subject's PHI will be available or shared with any other entity or individual than the study personnel. Only the data points of interest will be available for analysis. As soon as all data points are entered into the research database, a master linking list will be maintained that links each subject's medical record number with their study number. Subjects not meeting the more specific inclusion/exclusion criteria will be removed from the list and no data recorded.

HIPAA Authorization from subjects will be wrapped in with the permission/assent/consent form.

22.0 Compensation for Research-Related Injury - N/A

23.0 Economic Burden to Subjects

All procedures, treatments, medications and clinic visits involved in this study are part of usual medical care. Subjects will not have to pay anything extra to participate in the study. There are no additional costs to the subject's guardian or the subject's insurance.

This study does not pay for any of the costs of the subject's care. The subject's insurer will be responsible for all costs related to their treatment, including but not limited to surgery, medications, follow-up visits, imaging and any other related expense. The subject's guardian(s) will be responsible for any costs the subject's insurer does not cover. If the guardian(s) has any questions about these costs or what out-of-pocket expenses they may be responsible for, they should contact the subject's insurer or hospital billing office.

24.0 Permission/Assent/Consent Process

The process of informed permission, consent and assent will take place at patient bedside prior to discharge from the hospital.

Permission will be attained from a parent. The 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. Permission will not be obtained from individuals other than parents.

After a parent has given permission for their child to participate in the study, assent will be attained from some children involved in this study according to the regulations outlined in the CMH Research Policy and Procedures. Assent will be attained from children 7 years of age and older. Assent for these children under 7 years of age is waived under 45 CFR §46.408(c)/45 CFR §50.55(c) for this study. The research involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration and whenever appropriate the subjects will be provided with additional pertinent information after participation.

25.0 Process to Document Permission/Assent/Consent

This study will document permission/assent/consent as outlined in "CM Research Policy 10.04 Obtaining Permission/Assent/Consent."

26.0 Setting

Eligible subjects will be identified and recruited at Children's Mercy Adele Hall Campus. Subjects may present directly to CMH or be referred to CMH from other hospitals for evaluation and surgical intervention. All surgical interventions will be completed at CMH. Subjects will be seen for follow-up visits in the Orthopedic Surgery Clinic most convenient for them at either CMH, CM-Kansas, CM-Northland or CM-East.

This protocol, and any subsequent modifications, will be reviewed and approved by the Pediatric IRB at The Children's Mercy Hospital & Clinics.

The study may be modified or discontinued at any time by the IRB, the Office for Human Research Protections, the United States Food and Drug Administration or other government agencies as part of their duties to ensure that research subjects are protected.

We will be using an IRB approved flyer-notification for CMH staff that will be working with this population so they are aware of the study and to notify the research coordinator of possible patients that should be screened.

27.0 Resources Available

Approximately 320 children with SCFs preset to CMH campus annually. Of those 320, approximately 150 are Gartland type III SCHFs. We anticipate 20%of those 150 will be ineligible for the study, miss enrollment or decline enrollment. The study team will be trained to obtain the permission/consent/assent and document the process in Cerner. All study members are current in the review of this study and its procedures. Caleb Grote, MD, PhD and Lisa Berglund, MD will work with the assigned investigators, consultants, and student/resident weekly to review the study progress. We plan to complete this project in 20-24 months from the start date.

28.0 Multi-Site Research – Study team members from local academic institutions such as UMKC & KUMC will assist on this project. A reliance will be established with I the home institution. The relationship with these institutions is for study team member education and experience purposes only. No subjects or research activities will occur onsite at the external academic institutions.

28.0 International Research - N/A

29.0 References

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