Title: Study Protocol with Statistical Analysis Plan

NCT number: Pending

Document date: 09/26/2023

GENERAL STUDY INFORMATION

Study Title

Include the study title below.

Video-Assisted Informed Consent for Neonatal Lumbar Puncture

1 Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.
***Note**: Expedited review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance:*
https://research.utexas.edu/ors/human-subjects/get-help/

a ☐ **Full Board Review – Greater than Minimal Risk Research**
b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypotheses

Please describe the research aims and hypotheses in the box below. To input text, click in the box below and start typing. Note: Procedures will be explained in a separate section below.

We hypothesize that having a visual aid (animated video) in addition to the verbal information presented in the consent process will lead to increased parent/guardian comprehension, decision-making, and satisfaction with the consent process for neonatal lumbar puncture.

3 Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

A neonatal lumbar puncture (LP), also known as a spinal tap, is a critical diagnostic procedure for detecting and managing serious infections such as meningitis in newborns[1]. Ensuring that parents and caregivers fully understand the procedure, its risks, and its benefits is an essential aspect of the informed consent process. Traditionally, healthcare providers have relied on verbal and written methods to communicate this information to parents, aiming to facilitate comprehension and obtain consent for the procedure[2]. However, there is growing evidence that these traditional methods may not always be sufficient in providing parents with a comprehensive understanding of the procedure, which could potentially impact the decision-making process and overall satisfaction with the care provided[3,4]. After conventional consent discussions, parents are still often not aware of what the procedure will entail, the risks, how long the procedure will take, and what outcomes to expect.

Language barriers can also contribute to misunderstandings during the consent process, even with the assistance of translation services.

Despite the importance of obtaining informed consent for neonatal LPs, there is a notable lack of research on the effectiveness of alternative methods for communicating this information, such as video-assisted consent. Video-based interventions have been shown to improve patient understanding and satisfaction in other medical contexts[5] and may provide a more engaging and easily accessible means of conveying complex information related to the neonatal lumbar puncture procedure. Integrating video-assisted consent into the process could potentially enhance parent comprehension, decision-making, and satisfaction with the consent process.

The purpose of this study is to explore the effectiveness of video-assisted neonatal lumbar puncture consent processes against a conventional consent discussion to inform parents about pediatric lumbar puncture in the pediatric ED. We hypothesize that having a visual aid in addition to the verbal information presented in the consent process will lead to increased parent comprehension, decision-making, and satisfaction with the consent process. Furthermore, the findings from this study may have broader implications for improving the informed consent process for other medical procedures and interventions in pediatric settings.

1. Leazer RC. Evaluation and Management of Young Febrile Infants: An Overview of the New AAP Guideline. *Pediatrics In Review*. 2023;44(3):127-38.
2. Katz AL, Macauley RC, Mercurio MR, et al. Informed Consent in Decision-Making in Pediatric Practice. *Pediatrics*. 2016;138(2):
3. Sherlock A, Brownie S. Patients' recollection and understanding of informed consent: a literature review. *ANZ J Surg*. 2014;84(4):207-10.
4. Richardson V. Patient Comprehension of Informed Consent. *Journal of Perioperative Practice*. 2013;23(1-2):26-30.
5. Spencer SP, Stoner MJ, Kelleher K, Cohen DM. Using a Multimedia Presentation to Enhance Informed Consent in a Pediatric Emergency Department. *Pediatric Emergency Care*. 2015;31(8):572-6.

4 Design and Methodology

Provide a brief description of the study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

A video-assisted informed consent intervention will be implemented in the Dell Children's Medical Center (DCMC) Emergency Department (ED). Parents whose children are recommended for LP will be randomly selected to receive either standard informed consent procedures or video-assisted informed consent. We plan to enroll 100 participants. The intervention group (n=50) will receive procedure information via a video and the control group (n=50) will receive standard procedure explanation. The 2-minute video (available in English or Spanish) will use animation to explain the neonatal LP procedure, benefits, and risks.

All participants will complete brief knowledge surveys after the intervention and will be asked to provide feedback on their satisfaction with the informed consent process. Pediatric emergency medicine physicians at Dell Children's collaborated to create the knowledge surveys using the Delphi method. The primary outcome to be assessed is the efficacy of the video intervention on parents'

comprehension compared to the conventional discussion. Secondary outcomes will focus on parental satisfaction with the informed consent process and the rate of consent refusal.

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

Data collection and analysis will be performed by the study physicians with the support from research personnel and faculty at DCMC. Summary statistics of patient variables will be performed using means with standard deviations (normally distributed data), and medians with interquartile ranges (non-normal data). Categorical data will be presented as percentages. An independent sample t-test will be used to analyze the differences between the survey scores, and the Wilcoxon rank-sum test will be used to compare each groups satisfaction with the discharge process. If significant differences in baseline variables are observed between the groups, multivariate logistic regression modeling of the data will be utilized to adjust for potential confounders.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Check each research procedure included in your study. A full description of all study procedures should be provided in the Procedures (Details) section below. Procedures denoted with "" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☐	Bio-specimens*	☐	Biometrics	☐	Registry or Repository*
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research*	☒	Interview/Survey	☐	MRI
☒	Protected Health Information*	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☒	Record Review	☐	Sensors (Inserted)	☐	Sensors (Externally Placed)
☐	Audio (only) Recording	☐	Video Recording	☐	X-Ray/CT/DEXA

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.
A full description of all study interventions should be provided in the Procedures (Details) section below.
** Interventions denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☒	Behavioral	☐	Device*	☐	Drug/Biologic*

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Check the box(es) below if you are implementing research procedures that require oversight from additional UT committees.

☐ **Energy introduced to the subject (electrical, magnetic, light)**

☐ **Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos**

☐ **Radiation exposure without direct clinical benefit**

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus UT IBC approval is needed.

a ☐ **UT IBC has (or will have) oversight.**

Provide UT IBC Number:

b ☐ **Biological samples collected will not be stored at UT Austin and another agency has responsibility for biospecimen safety.**

10 Alternatives to Participation in This Study

Provide a description of alternatives to participation in this study, as applicable.

Participation in the study is voluntary. All patients will be treated for their presentation. Parents of patients who choose not to participate will receive standard hospital informed consent procedures.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- *Description of all research procedures being performed and when they are performed, in sequential order.*
- *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- *Secondary data or specimens that will be obtained, how they are collected, how are they used.*
- *Where research activities will take place and duration (include expected time commitment of participants).*
- *Study elements checked in #6 above should be described here.*

Note: if this is a multi-site or collaborative study include the following:

- *This is a "Multi-site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a collaborative study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- *For assistance with multi-site/collaborative research, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

All English- or Spanish-speaking parents/guardians of patients, 0-7 months of age, who are recommended for lumbar puncture during the study period will be approached to participate. Following consent, patients will be randomized to receive standard hospital informed consent procedures for neonatal LP or video-assisted informed consent. Computerized randomization functions and opaque envelopes will be used to achieve random assignment and allocation concealment.

The control group will be given the standard conversation informed consent along with Q&A time. The form used for this discussion and consent process is a form provided by Ascension Seton/DCMC titled "*Disclosure and Consent for Lumbar Puncture*." The intervention group will also be given the standard conversation informed consent (with the "*Disclosure and Consent for Lumbar Puncture*" form) and will also be shown a 2-minute video in either English or Spanish with information on the procedure, risks, and benefits and then given an opportunity to ask their provider any questions. The video is pending being created until all IRB and administrative approvals of the protocol are obtained; the video will be submitted to the IRB as a modification once created and finalized.

Both groups will sign and receive the hardcopy consent form and information form (per Ascension Seton and DCMC protocol) and will have the opportunity to ask their provider questions as much as needed. No script exists for the standard consent process as providers use the "*Disclosure and Consent for Lumbar Puncture*" form and their own words to describe the process. As we only want to assess whether including the video in the consent process makes a difference in parent/guardian understanding and satisfaction, we are not providing a formal script for providers to use in either the control or intervention group.

Both groups will receive a survey to assess knowledge about the procedure after the informed consent process. The surveys will also be offered in either English or Spanish depending on the caregiver's preference. The survey will also contain questions about satisfaction with the way information about the procedure was presented.

The time required for each group is approximately 30 minutes: 15 minutes for the consent procedure (with or without the video) including Q&A, and 15 minutes to complete the post-consent survey.

PHI that will be collected as part of the study includes: medical record number (MRN), visit date, race/ethnicity, diagnosis precipitating the need for the LP, and date of birth (to calculate age at visit).

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box for each population, if they are specifically studied for this research.

☐ Active Military Personnel	☒ Children/Minors	☐ Decisionally Impaired Adults
☐ Emancipated Minors	☐ Fetuses	☒ Individuals with Limited English Proficiency
☐ Neonates (Uncertain Viability)	☐ Neonates (Non-Viable)	☐ Prisoners
☐ Pregnant Women	☐ UT Staff/Employees	☐ UT Students

13 Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

Parents/guardians of children 0-7 months old who are recommended for a lumbar puncture will be put into two groups to receive either:
1) standard consent conversation or
2) video-assisted consent

b Minimum Age

Include the minimum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state the minimum age for each group.***

Minimum age of child = 0 days (both groups)
Minimum age of parent/guardian = 18 years old (both groups)

c Maximum Age

Include the maximum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state maximum age for each group.***

Maximum age of child = 7 months (both groups)
Maximum age of parent/guardian = 85 years old (both groups)

d Inclusion Criteria

Describe the specific criteria that will be used to decide who will be INCLUDED in the research from interested or potential subjects. Define technical terms in lay language, as applicable.

Children, age 0-7 months old who are recommended for lumbar puncture procedure during an ED visit.
Caregiver fluent in English or Spanish

e Exclusion Criteria

Describe the specific criteria that will be used to decide who will be EXCLUDED from the research. Define technical terms in lay language, as applicable.

Previous enrollment in the study, i.e., the patient has been previously part of the current LP study. This will be confirmed by the study coordinator, PI, or co-I.
Parent/guardian unwilling to complete surveys

14 Total Sample Size

Enter the total target sample size below.

100 children and their parent/guardian will be part of the study (50 in each group)

15 Sample size rationale

Describe your sample size rational below.

Since this is a pilot study, we do not have the necessary background information to conduct a formal sample size calculation. Given our current rate of lumbar punctures in this target population, we expect to enroll 100 subjects (50 per arm) over a one year period.

SCREENING AND RECRUITMENT

16 Identification and Screening

*Check the box below if this study involves a screening process **prior** to the informed consent process.*

☐ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**
1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Identification and/or Screening Procedures

Describe the identification and/or screening procedures below.

Providers (MDs and DOs) who are part of the Pediatric Emergency Medicine Fellowship at DCMC will be trained on eligibility criteria for the study and asked to identify potential study candidates who are under their care. Patients are triaged upon arrival at the ED by nursing staff and a preliminary diagnosis and acuity level is assigned to the patient before they are seen by the ED provider. While this triage information is available to all providers on call in the ED and patients are assigned to a provider based on acuity level of the patient, use of electronic medical records/PHI will not be used to identify potential participants. If they are not part of the research team, ED providers will reach out to research personnel to approach the patient about the study if, in the provider's clinical judgment, a lumbar puncture will be part of the patient's treatment plan. A trained enrolling researcher will approach patients and their parent/guardian to introduce the study. If a patient agrees to participate, the enrolling researcher will communicate this to the patient's designated provider. Research studies are common in the DCMC ED, and this process has been used for other studies, as well. IRB-approved studies where this recruitment method has been used includes:

- 00002014 - MeMed BV™ to Aid in the Reduction of Inappropriate Antibiotics in Pediatric Community Acquired Pneumonia

- 00000904 - Outcomes of Pediatric Facial Laceration Repair Using 6-0 Fast Absorbing Gut Sutures with and without Steri-strips: A Randomized Controlled Trial
- 00003676 - Effect of Home Nebulized Albuterol vs. Supportive Care on Unscheduled Return Visits in Infants with Viral Bronchiolitis

18 **Recruitment Overview**

Check box indicating all recruitment methods utilized for this research.

☐	E-mail	☐	Flyer
☒	In-Person	☐	Letter
☐	Social Media	☐	Research Pool
☐	Telephone/Text	☐	Snowball Sampling
☐	Web-post	☐	Word of Mouth

19 **Describe the recruitment process, including where recruitment will take place.**

Describe recruitment procedures in the box below. Describe all elements checked above to provide a complete understanding of the recruitment strategies/methods.

NOTE: Upload copies of all recruitment materials to UTRMS-IRB in the "Recruitment Materials" section.

Recruitment will take place at the DCMC ED. All patients with an emergency department recommendation for LP will be evaluated for study enrollment. If meeting inclusion and exclusion criteria, the patient and caregiver will be approached by an enrolling researcher. The enrolling researcher will inform the family about the study, including providing a written explanation. Refusal to participate will not affect the quality of care they will receive. No recruitment materials will be used when approaching potential participants.

OBTAINING INFORMED CONSENT

20 **Consent Overview**

Check the box(es) for consenting procedures that will be used.

☒	Obtaining Written Informed Consent/Parental Permission	☐	Requesting a Waiver of Documentation of Informed Consent
☐	Requesting a Waiver of Informed Consent	☐	Requesting an Alteration of the Required Elements of Informed Consent
☐	Obtaining Child Assent	☐	Obtain Consent Using a Short Form with a Witness

21 Consent and Assent Processes

Provide a detailed description of consent/assent procedures in the box below. Include: who will obtain consent, where will consent be obtained, how is consent obtained, how consent/assent is documented, and when the consent process will occur in such a manner that participants will have sufficient time for adequate consideration.

Enrollment will take place in the patient's room at the DCMC ED. An enrolling researcher will explain the study objectives, risks, benefits, and alternatives to families in person. If the patient is Spanish speaking, a HIPPA-certified video or telephonic translator may be used if a bilingual study coordinator is not available. Use of HIPPA-certified video (specifically, the MARTII system) or telephone translator is standard procedure for all translation services at DCMC (and Ascension Seton facilities) whether it is for clinical, research, or administrative use. Families will be provided a written consent form, with similar explanation and be given time to review prior to being given the opportunity for questions. If families agree to participation, signed consent will be obtained by research personnel.

Potential participants may be the enrolling researcher's patient. To minimize the potential for undue influence in these cases, the enrolling researcher will reiterate that participation in any research study is completely voluntary and that participating or not participating will not have any effect on the level of care the child receives at DCMC.

22 Electronic Consent

Check the box below if this study involves obtaining consent with an electronic signature. Be sure the section above is consistent. NOTE: This box should NOT be checked participants are responding "yes" or clicking "I Agree" on a consent form. ***This section should only be completed if an electronic signature is being obtained.***

☐ **This study involves documenting informed consent/parental permission using an electronic signature.**

If true, specify method for obtaining e-consent below (e.g., DocuSign):

23 Consent and Translation

Check the box below to indicate that consent documents/scripts will be translated to a language other than English.

☒ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

If above is checked, complete the below information describing the translation process. Either A or B must be checked.

A ☐ **The consent documents will be translated by a certified translator.**

B ☒ **A non-certified translator will translate the consent documents.**

If selected, complete the next two items below. Section describing qualifications must be completed and backtranslation (ii) must be true.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

The consent form has been translated by the study coordinator Lina Palomares, LMSW. Ms. Palomares is fluent in Spanish and has 20 years of experience in survey design and translation.

ii ☒ **Another individual will confirm that the translation is accurate and appropriate**

26 Waiver of Documentation of Informed Consent

*Only complete this section if a waiver of documentation of consent is requested (checked above in #21). To approve a waiver of documentation of consent, one of the following options must be appropriate and justified by the researcher. Please choose **one** waiver option and provide additional information as prompted. **Waiver option 2 is most common.***

A Waiver Option 1

Check the box below for each item (all required – #1-4) and provide protocol-specific information as to how the criteria below are met.

NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 1 criteria, you will need to obtain written consent.

1 ☐ **The only record linking the subject and the research would be the consent document.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

4 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants.

B Waiver Option 2

Check the box below for each item (all required – 1-3) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The study is minimal risk.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **Written consent would not be required outside the research context.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants.

i

C Waiver Option 3

Check the box below for each item (all required – 1-4) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

i **Describe the cultural group or community.**

2 ☐ **The research presents no more than minimal risk of harm to subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

4 **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

27 Waiver or Alteration of Informed Consent

Only complete this section if a waiver or alteration of consent is requested. *To approve a waiver or alteration of consent, all of the following criteria must be appropriate and justified by the researcher.* ***All boxes must be checked.*** *SKIP THIS SECTION IF NOT REQUESTING A WAIVER/ALTERATION OF CONSENT*

A ☐ **The research involves no more than minimal risk to the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

B ☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

C ☐ **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining consent is required and not just impracticable to obtain consent).**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

D ☐ **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.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

28 Deception/Incomplete Disclosure and Debriefing

Only complete the sections below if requesting an alteration of informed consent for research that involves deception/incomplete disclosure.
Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.
Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.
See IRB Policies and Procedures Section 15 for a description of deception.
If this study does not involve deception/incomplete disclosure, skip this section.

A ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive the subject to the nature of the study).**

B ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

C **Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

D **Describe debriefing procedures.**

To input text, click in the light grey area below. ***NOTE: Upload the debriefing form to UTRMS-IRB in the "Consent Forms" section.***

BENEFITS

29 Benefits to Society

Describe the scientific and societal benefit(s) below.

The potential benefit of this trial would be the identification of a superior method for providing information on lumbar puncture procedure, risks, and benefits to parents and guardians. Video-assisted consent could also be adapted for other procedures within the Pediatric ED to improve caregiver understanding of procedures.

30 Potential Direct Benefits to Participants

Click on the applicable check box. A or B must be checked.

A ☐ **There is no anticipated direct benefit to participants.**

B ☒ **There are anticipated benefits to participants.**

i **If applicable, describe the potential direct benefits to participants.**

Describe potential direct benefits to participants below.

If the video-assisted consent procedure provides information on lumbar puncture in a more understandable way, parents/guardians in the intervention group may have better understanding of the procedure, feel more secure in the procedure their child will receive, and have higher satisfaction with the ED visit.

RISKS

31 Describe the risks associated with each activity in this research

To input text, click in the light grey area below. Note: Risks should also be outlined in the consent form(s).

The greatest risk for participants is loss of confidentiality. Other risks include discomfort watching the animated video, completing the study survey, or being provided with the verbal information about LPs. The LP procedure itself (whether part of the research study or not) carries risks, as well.

There is no risk the additional time spent watching the video (for the participants randomized to that arm) will delay care for patients. Even with the standard consent process, the time spent going over the document, answering questions, and clarifying the procedure varies greatly from family to family and the procedure is not conducted until the consent is obtained. We do not anticipate that watching the video (which will run no more than 2 minutes) will impact the overall time spent on the process significantly.

32 Describe how each risk is mitigated/minimized.

To input text, click in the light grey area below. Note: Risks mitigation should be outlined in the consent form(s), as applicable.

The risk of loss of confidentiality does exist but will be minimized with previously mentioned data protection procedures and de-identification plans. Risks associated with discomfort will be mitigated in the same manner as when explaining invasive procedures in the clinical setting, e.g., allowing the parent to ask questions about the procedure to the provider, providing the parent with Child Life supportive services, providing parent with other support resources, getting a second opinion about the procedure, etc.

Risks involved with the LP procedure are discussed with the parents/guardians irrespective of whether it is part of a research study or not. Parents/guardians are given an overview of these risks, benefits, other options for care, and are given the opportunity to ask questions and voice concerns with their child's doctor. Social Work and Child Life is also available to help discuss concerns.

33 Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

One of the following must be checked (A, B, or C).

A ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

B ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan to monitor for safety (Data Safety Monitoring Plan (DSMP)).**

Complete Data Safety Monitoring Details

C ☐ **This study has a Data Safety Monitoring Board (DSMB).**

*Complete Data Safety Monitoring Details section below **or** upload this study's Data Safety Monitoring Board's charter that contains the information below.*

34 Data Safety Monitoring (Details)

*Complete this section if the study has a Data Safety Monitoring Plan. **SKIP this section there is not a DSMP/DSMB.** If the study has a DSMB, ensure all items below are addressed in the charter (and charted uploaded to UTRMS-IRB) or provide additional information below, as needed.*

A **How is safety information collected?**

B **When will safety data collection start (for each participant or for the whole study, as applicable)?**

C **How frequently will safety data be collected?**

D **Who will review the data for safety?**

E **How frequently will data be monitored for safety concerns?**

F **What data will be reviewed?**

G **State the frequency or periodicity of the review of cumulative data.**

H **State any conditions that would trigger an immediate suspension of the research.**

35 Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to next section. Include this information in your consent form.*

A **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

B **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

36 Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.

REQUIRED DISCLOSURES

37 Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form.

A ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**
Add appropriate disclosure in consent form(s).

B ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**
Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for information and download the Title IX Reporting Form on the Special Topics page.

C ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**
Add appropriate language to consent form(s).

i **Articulate methods for addressing and reporting incidental findings, if applicable.**
Ensure appropriate information is in consent form(s), as applicable.

PRIVACY AND CONFIDENTIALITY

38 Privacy

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants. Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.

All initial research interactions with the patient will take place in a private room within the DCMC ED. Patients will only be approached once a trained ED provider has verified the patient's eligibility for research personnel to approach. We will collect private information (e.g., name, medical record number) to be able to review the patient's visit history after discharge from the ED.

All post-study activities, including chart review and data analysis will occur in a confidential location, specifically the PEM Fellows offices at Dell Children's Medical Center. The suite has individual offices, including a private office for the study coordinator, that ensures that phone conversations cannot be overheard, and data being assessed on a computer monitor cannot be seen by others.

All data will be analyzed in a de-identified format. Upon study closure, identifiers will be destroyed. The data from this study may be published, but the subject identities will not be disclosed.

39 Confidentiality and Data Security Plan

Provide general information below regarding confidentiality and data security plan. Provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.
Include the following, as applicable:

- *If identifiers will be coded to protect confidentiality describe how and where identifiers are stored.*
- *Describe where and how data is stored and maintained.*
- *Include details regarding storage of consent forms, if applicable.*

Research personnel will have access to identifiable data, specifically MRN, visit date, date of birth (to calculate age at visit date), and medical diagnosis precipitating the need for the LP. Data will be coded and de-identified after the data preparation and collection stage. A unique ID number will be assigned to each subject included in the study. The PI will maintain a list correlating patient medical record numbers to the unique ID numbers to assist in quality control of the data. This file will be stored separately from the health information in the analysis file. Electronic data will be stored in UT Box.

Survey data and consent forms will be stored in the PEM Fellows office, which is accessible only via badge entry to authorized personnel, in a locked filing cabinet accessible only to study personnel.

40 Research Data/Records Destruction Details

Confirm general research data/information (including consent forms, as applicable) destruction timeline. ***One of the following must be checked.***

☒ **Research Data/Records will be retained for 3 years after study completion per UT record retention policy.**

☐ **Research Data/Records will be retained for longer than 3 years and retention information is provided below.**

Describe data retention timeline below. To input text, click in the light grey area below.

41 Confirm identifiable data destruction details

One of the following must be checked.

☒ **Identifiable data will be destroyed.**

If checked, ensure the below section describes identifiable data destruction plan and timeline.

All identifiable data will be destroyed upon completion of the study. Consent forms will be retained for three years.

☐ **Identifiable data will not be destroyed.**

If checked, explain below the rationale for retaining identifiable data indefinitely.

42 Data Access

If you plan on creating a repository, complete the repository form as well (download from in UTRMS-IRB).

☒ **Study Team Members** ☐ **External Collaborators** ☐ **Data coordinating center**

☐ **Sponsor** ☐ **Future Sharing with other researchers**

☐ **Others**

43 Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data.

To input text, click in the light grey area below. Ensure that data sharing and future use is addressed in the consent form(s).

Only the principal investigator, co-investigator, and research coordinator will have access to identifiable information. Data will not be shared outside the research team.

44 Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip this section.

A ☐ **NIH has issued a Certificate of Confidentiality for this study.**

Ensure CoC language is included in the consent form(s).

B ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

Ensure appropriate CoC language is included in consent form(s). Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must update the consent form language and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

COMPENSATION AND COSTS

45 Compensation

Click on the check box (or double click and type an "X" if using Google Docs). A or B must be checked.

A ☐ **Subjects receive compensation.**

i ☐ **Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.**

ii Total Amount of Compensation

Include the total amount of compensation below.

iii Type of Compensation

☐ **Cash** ☐ **Check** ☐ **Gift Card**

☐ **Course Credit** ☐ **ClinCard** ☐ **Tango Card**

☐ **Other**

Describe other form of compensation below.

iv Proration Schedule

Describe the proration schedule for multi-visit/session studies. Skip if not applicable.

B ☒ **Subjects will not receive compensation.**

46 Costs

A or B must be checked.

A ☐ **Participants will have no costs associated with this study**

B ☒ **Participants will have the following costs associated with this study.**

☒ **Standard of care procedures contributing to study data**

☐ **Research procedures not associated with standard of care**

☐ **Administration of drugs / devices**

☐ **Study drugs or devices**

☐ **Transportation and parking**

i **Describe all costs below.**

To input text, click in the light grey area below.

Patients or their insurance will be required to cover the cost of the visit as part of usual care. Uninsured patients will be given the option to enroll in Medicaid or another public program prior to discharge to minimize this cost.