THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

Title: Quadratus Lumborum Blocks for Pain Control following Open Ventral Hernia Repair: A Double Blinded Randomized Control Trial

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1.0 INTRODUCTION

Ventral hernia repair (VHR) is a common procedure often associated with significant post-operative pain, impacting opioid consumption, patient satisfaction, and longer hospital stays. Opioid consumption poses risks, including nausea, emesis, dizziness, drowsiness, hypotension, ileus, and constipation.[1] The number of VHR surgeries in the United States has nearly doubled since 2006, reaching 611,000 annually, with an estimated annual cost of $9.7 billion[2]. Adequate pain control is crucial for patient outcomes, safety, and quality of life, potentially influencing hospital stay and cost. However, there is no established superior approach for perioperative pain management after VHR. There is a lack of published data on the effects of quadratus lumborum (QL) blocks for this patient population. An unpublished, retrospective analysis of our institutional data indicates that patients consume less than half the amount of morphine milliequivalents (MME) in the first 24 hours after open abdominal wall reconstruction when receiving QL blocks. Publication of this data is underway. Therefore, it is worthwhile to prospectively study the efficacy of QL blocks in patients undergoing open VHR, as this could significantly reduce post-operative opioid consumption, improve pain, decrease the length of hospital stay, and reduce hospital costs

2.0 RATIONALE

QL blocks have provided analgesia for upper and lower abdominal surgery. These blocks involve ultrasound-guided local anesthetic injection deep into the anterior fascia of the quadratus lumborum into the thoracolumbar fascia, resulting in widespread abdominal and pelvic pain control. QL blocks extend that coverage from T4 to L1 in the paravertebral space. QL blocks provide complete sensory analgesia for most patients from T9-L1.

VHR pain control heavily relies on perioperative opioids, but the adverse short- and long-term effects of opioids has prompted physicians to adopt alternative analgesic techniques.[1,2] Other pain control methods such as spinal anesthesia, epidural analgesia, and various regional and local anesthetic techniques have drawbacks making them less beneficial for the entire perioperative period.[3] Regional blocks like QL offer advantages over spinal and epidural anesthesia, including earlier ambulation, less need to disrupt deep vein thrombosis prophylaxis dosing, reduced length of stay, and earlier resumption of daily activities.[4]

Minimal investigation has been conducted using QL blocks in ventral/incisional hernia repair operations. QL blocks have been demonstrated to provide perioperative pain control in umbilical hernia repairs and other abdominal procedures.

Outcomes of QL blocks for VHR have yet to be studied in a randomised control trial. Another study found that QL blocks had longer analgesic durations which resulted in shorter hospital stays.[5] A third study found greater dermatomal spread with QL blocks but no difference in long-term pain.[6] The last study found that QL blocks provided better postoperative analgesia, improved pain scores, and longer analgesic durations.[7] In conclusion, recent literature suggests that QL blocks may provide better post-operative pain control without compromising safety or significantly altering costs. However, the efficacy of QL blocks for patients undergoing open VHR has yet to be established. This is the first prospective study to evaluate the effectiveness of QL blocks in this patient population.

3.0 TRIAL OBJECTIVES

Hypothesis: QL blocks are effective in reducing acute postoperative pain as measured by morphine milligram equivalent (MME) consumption in the first 24 hours following ventral hernia repair compared to placebo.

3.1 Primary objective

- Compare total MME opioid utilization in the first 24 hours after open ventral hernia repair in patients receiving QL blocks versus placebo blocks.

3.2 Secondary objectives

Determine the difference between QL versus placebo for the following:

- Total inpatient MME used
- Daily numerical rating scale (NRS) until the day of discharge
- Hospital length of stay after surgery
- Perioperative complications (intra-operative, post-operative: wound complications, bowel obstruction, urinary retention requiring catheterization, venous thromboembolism, ileus requiring nasogastric tube placement, bleeding, cardiopulmonary, renal failures, sepsis, death, readmissions)
- Opioid use within 30 days after surgery
- Validated patient reported outcomes (PROMIS 3a SF and HerQLes)
- Accuracy of a blinded surgeon to predict the type of block on post-op Day 1
- Accuracy of blinded patient to predict the type of block on post-op Day 1.

3.2 Outcomes:

The primary outcome is total morphine milligram equivalent (MME) consumption recorded in milligrams (mg) during the first 24-hour post-operative period.

Secondary outcomes are:

- Daily numerical rating scale (NRS) until the day of discharge
- Perioperative complications
- Hospital length of stay
- Opioid use at 30 days
- Patient reported outcomes (PROMIS 3a SF and HerQLes)
- Accuracy of a blinded surgeon provider to predict the type of block on post-op Day 1
- Accuracy of blinded patient to predict the block type on post-op Day 1.

4.0 STUDY PLAN

4.1 Study Design

This is a prospective, double-blinded, randomized, placebo-controlled clinical trial comparing QL blocks to placebo for pain control for patients undergoing open VHR.

4.2 Study Duration

Based on our review of MME usage in patients who received QL blocks compared to those who received no blocks, the study will 35 patients per arm (70 patients total) for an alpha of 0.05, beta of 90% and an estimated 10% attrition rate. The total study duration is estimated at 6 months. Recruitment will take place with potential patients coming from a pool of high-volume hernia surgeons. For reference, this group of surgeons performs 600 hernia surgeries per year. We anticipate that approximately 15-20 patients will be randomized per month. The study duration is estimated to last approximately 12 months post IRB approval and study initiation.

4.3 Selection of Study Participants & Informed Consent

Patients at the UT Medical Center who meet the predefined inclusion and exclusion criteria will be asked for their consent to participate in this study at the time of their preoperative visit in the surgeon's office. The nature and purpose of the study will be explained to the patient by one of the delegated study personnel and the patient will be given a copy of the informed consent to review. The investigator or study coordinator will answer any questions which the patient may have prior to their signing the consent form. The signed informed consent form will be kept in the patient's research chart and a copy, signed by an investigator will be given to the patient.

4.4.1 Inclusion Criteria

1. >18 years of age
2. Able to read and understand study procedures
3. Willing to participate and sign an informed consent form
4. Open approaches to ventral hernia repair
5. Clean (CDC Class I), clean-contaminated (CDC Class II)
6. Elective surgery
7. Mesh placed in the retromuscular position

4.4.2 Exclusion Criteria

1. Dirty-Infected cases (CDC Class IV): Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera

2. Patient has a contraindication to receiving the drug and/or procedure: allergy/sensitivity to the drug, coagulopathy, abdominal wall infection at the drug administration site, systemic infection, anatomical distortion, neuropathy
3. Emergent procedure
4. Mesh not placed

4.5 Discontinuation of Subjects

An individual patient is to be withdrawn from the trial if any of the following criteria apply:

- The patient withdraws consent, without the need to justify the decision
- The patient is no longer able to participate for medical reasons (e.g., surgical re-intervention, adverse events, or other diseases)
- Decision by the PI to discontinue a specific patient for his/her safety (e.g., in case of adverse events)

Data of patients who discontinue or withdraw after enrollment will be documented and the reason for withdrawal will be recorded in the study record. The data will be included in the study database and will be reported to the IRB.

5.0 STUDY PROCEDURES

5.1 Screening Assessments

The screening process will involve:

- Surgeon review of patient's medical history, pre-operative imaging and clinical exam to assess for eligibility criteria.
- Confirmation of patient eligibility by PI or delegated study personnel on the standard eligibility form
- Informed Consent obtained by delegated study personnel during the pre-operative clinic visit

5.2 Informed Consent/Enrollment

The delegated study personnel (Surgeons or Clinical Coordinator(s)) will present the study information to all eligible patients during the pre-operative clinic visit and will explain the purpose, risks, and benefits of the study to the patients and present them with an IRB approved Informed Consent Form (ICF). The participant will be given ample time to read the ICF and all questions and concerns will be addressed by an Investigator. After the patient signs the ICF, an investigator signed copy will be given to them for their records. Participants will be informed that they can withdraw their consent and decline participation in the study without any effect on their health care.

6.0 Randomization

On the day of surgery, when the patient arrives in the pre-operative holding area, randomization will

take place by the pharmacy team who prepares the syringes for the blocks. The blinded syringes will be given to the anesthesiologist who will perform the blocks (QL or Placebo). All study personnel, except for the pharmacists, will be blinded. Therefore, the anesthesiologist, surgeons and patients will be blinded as to which syringe contains active local anesthetic or saline.

7.0 INTERVENTIONS/GROUPS

Study Intervention Administration

Using standard protocols and procedures for block administration, the QL or Placebo blocks will be administered by the anesthesiology team in the pre-operative holding area just prior to surgery. In each intervention group (QL or Placebo), two syringes will contain either 29 mL of 0.25% Ropivacaine with 4 mg (1 mL) of Decadron (active arm) or 30 mL of preservative-free normal saline (placebo arm). Each pair of syringes, totaling 30 mL per syringe, will be administered as 30 mL to the right side of the abdominal wall and 30 mL to the left side of the abdominal wall for each patient. As previously mentioned, the anesthesiologist, surgeon and patient will all be blinded as to whether the block syringe is filled with the local anesthetic/dexamethasone solution or the preservative free normal saline placebo. Patients will be randomized into QL block and Placebo groups on a 50/50% basis. After receiving the QL or placebo block in the pre-operative holding area by the anesthesiology team, the patient will proceed to the operating room and undergo open ventral hernia repair. No local anesthetic will be administered in the operating room.

The current standard of care for perioperative pain control for abdominal operations is multimodal pain control. All patients in this trial will receive the standard multi-modal pain control perioperatively. If patients are randomized to receive QL blocks, this is administered in addition to the standard of care. The multimodal pain control regimen will be administered per the surgeon's discretion. The typical regimen consists of acetaminophen, muscle relaxant, NSAIDs and as needed (PRN) opioids. This is dependent on the patients' allergies and will be adjusted per surgeon discretion to provide a safe treatment plan.

The pharmacist will use a table pre-populated with the randomization assignments with space to fill out patient information and medication information on the day of surgery. This chart will be in paper form and kept in a research binder in the OR pharmacy. Each qualifying patient will be documented on the subsequent row in the table, maintaining the original order of randomization as dictated by the statistician. Based on the assignment, the pharmacy technician will be instructed as to which products to make in the sterile hood. The pharmacist will verify that the products were made appropriately and will label the syringes according to assignment. These documents will also be kept in a secure electronic format if deemed appropriate.

Intervention (Treatment arm): Active QL Block

The intervention arm will receive bilateral quadratus lumborum blocks in the preoperative holding area prior to surgery. Two separate 30mL syringes will contain 29 mL of 0.25% Ropivacaine with 4 mg (1mL) of Decadron. The anesthesiology pain team provider will administer 30 mL on the left side and 30 mL on the right side of the abdominal wall. The patient will receive one injection site per flank. During the procedure, the patient is placed in the left and then right lateral decubitus position and the ultrasound probe is placed above the iliac crest at the mid-axillary line. The pain team provider will move the probe posteriorly to identify the "shamrock sign." Under ultrasound guidance, a needle is inserted in an in-plane approach through the quadratus lumborum (QL) muscle until reaching the middle of the thoracolumbar fascia layer between QL and psoas muscle. After negative aspiration for blood, injection will allow the spread of local anesthetic between the QL and psoas muscle on each side.

Control (Placebo arm): Placebo QL Block

The control (placebo arm) group will undergo the same QL block procedure described above in the intervention arm, except saline (placebo) will be injected.
Therefore, the placebo control arm will also receive bilateral quadratus lumborum blocks in the preoperative holding area prior to surgery. However, the two syringes will instead contain a total of 60 mL of saline. The anesthesiology pain team provider will administer 30 mL on the left side and 30 mL on the right side of the abdominal wall. The patient will receive one injection site per flank. During the procedure, the patient is placed in the left and then right lateral decubitus position and the ultrasound probe is placed above the iliac crest at the mid-axillary line. The pain team provider will move the probe posteriorly to identify the "shamrock sign." Under ultrasound guidance, a needle is inserted in an in-plane approach through the quadratus lumborum (QL) muscle until reaching the middle of the thoracolumbar fascia layer between QL and psoas muscle. After negative aspiration for blood, injection will allow the spread of local anesthetic between the QL and psoas muscle on each side.

8.0 Follow Visit/Collection Time Points (post-operatively at 24 hours and 30 days)

Follow-up visit assessments will be completed at 24 hours and 30 days post-operatively. The study coordinator will review the subject's concurrent medication and medical history. A phone call will be made to patients who are discharged prior to 24 hours. They will be asked the same questions on the pain diary. They will question the subjects for any possible adverse events. If adverse events are reported, the PI will assess for causality, severity, intervention, and outcomes.

The following data will be collected:

- Intra-operative complications
- Aggregated mean post-operative numerical rating score (NRS) at 24 hours
- Opioid use and NRS collected by nurses for the open surgery and by the patient in a postoperative diary supplied to the patient at discharge for open surgery recorded as

cumulative MME and NRS at 24 hours

- Hospital length of stay after surgery
- Total perioperative complications (wound complications, bowel obstruction, urinary retention requiring catheterization, venous thromboembolism, ileus requiring nasogastric tube placement, bleeding, cardiopulmonary, renal failures, sepsis, death, readmissions) will be monitored and reported at 30 days
- Time to return to work
- Patient reported outcomes: quality of life and patient satisfaction assessments (PROMIS 3a SF and HerQLes) documented at the first follow up visit
- Accuracy of a blinded surgeon provider to predict the type of block on post-op Day 1

At the time of discharge, patients will be instructed to take acetaminophen 3-4 times daily. Patients will also be prescribed a muscle relaxant to take every 4-6 hours and an opioid to take on an as-needed basis every 4-6 hours for 3 days. The total amount of opioid pills provided at discharge will be 12-18 pills (every 4-6 hours for 3 days).

9.0 STUDY SCHEMATIC

	Screen Visit/ Enrollment (in clinic)	Baseline (at day of surgery)	24 hrs post-op (±5 hours)	Day 30 (±10 days)
Informed Consent	x			
Demographics	x			
Inclusion/Exclusion	x			
Randomization		x		
Medical History	x	x		
Study Intervention Administration		x		
Aggregated mean of NRS			x	
CC Opiate Med (24, 30-day MMESs)	x	x	x	x
Survey Administration	x			x

10.0 RISK

10.1 Physical Risks

Although the interventions being used in this protocol have been well tested for efficacy and safety, and both are currently being used in the standard of care intraoperative treatment. However, there may be potential risks associated with participation. Any medical treatment can have temporary and permanent side effects and can cause unforeseen adverse reactions, intolerance, or worsening of co– morbidities (including, revealing unknown allergies), which could lead to an acute adverse event such as itching, prolonged length of stay. Any subject with known medical conditions, or on a concurrent medication in which the study interventions are not recommended, will be excluded from participation as per the exclusion criteria.

10.2 Intervention Risk

There is the potential risk of interventional failure for study participants. The study results may not support the primary hypothesis that in patients undergoing ventral hernia repair, a QL block is a superior analgesic compared to placebo block. It is possible that the QL block will prove to be less effective than the placebo block.

Complications associated with a QL or placebo block include: pain at the injection site, bleeding, hematoma, nerve injury – which could be temporary or permanent, catheter site infection, wound complication, damage to surrounding structures, uptake of bupivacaine into the systemic blood circulation (causing systemic toxicity), allergic reaction.

10.3 Psychological Risks:

A potential psychological risk could occur if patients feel a sense of coercion to participate in the trial. The likelihood is small, because patients will be assured in the informed consent document and face-to-face discussion that participation is purely voluntary and they can withdraw their participation at any time.

10.4 Research Risk

No identifiable patient information will be linked to patient assessments during the study. For this specific project, all information related to patients will be identified only by patient initials and study number. However, for research purposes, it may be required to collect PHI such as age, DOB, Medical Record Number and dates of diagnoses. Only the study team will have access to this data and it will not be shared with anyone outside of the study team. The greatest research risk, although rare, is the loss of confidentiality caused by unauthorized release or misuse of information from research records.

11.0 BENEFITS

Although there may be immediate clinical benefits for some patients in this study the anticipated primary benefit is the future potential to decrease the total MME utilization, improve the quality of life, and decreased time to work for patients undergoing ventral hernia repair.

Information obtained from this research may help patients in the future achieve better health outcomes and provide clinicians with pertinent information about post-operative opioid induced dependency.

12.0 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

Adverse events (AEs) that are considered possibly, probably or definitely related to the study procedure will be recorded in the CRFs. AEs will be assessed starting with onset, and evaluation will continue until resolution is noted, or until the investigator determines that the patient's condition is stable.

All AEs will be characterized by the following:

- AE name
- Start and Stop dates
- Relationship to study procedure
- Severity
- Action taken
- Outcome

Relationship

The investigators will assess the AEs, and using their clinical judgment will assign an attribution to the AE using the following categories:

- **Unrelated** – The AE *is clearly NOT related* to the study procedure
- **Unlikely** – The AE *is doubtfully related* to the intervention
- **Possibly** – The AE *may be related* to the study procedure
- **Probably** – The AE *is likely related* to the study procedure
- **Definitely** – The AE *is clearly related* to the study procedure

Severity

The severity of the AEs should be graded by the investigator as follows:

- **Mild** – Transient discomfort; no prescribed medical intervention/therapy required and does not interfere with daily activities.
- **Moderate** – Low level of discomfort or concern with mild to moderate limitation in dailyactivities; some assistance may be needed; medical intervention/therapy required.
- **Severe** – Discomfort and limitation in daily activities, assistance required; medical intervention/therapy required.

Action Taken

The action taken in response to the AE should be reported using the following categories:

- None
- Procedure or physical therapy
- Withdrawn from study due to AE
- Hospitalization
- Prescription drug therapy
- Non-prescription drug therapy
- Other (specify)

Outcome

The clinical outcome of an AE should be characterized as follows:

- Resolved without sequelae
- Resolved with sequelae (specify)
- Ongoing (i.e. continuing at time of study discontinuation)
- Death
- Unknown/lost to follow-up
- Other

SAE Reporting

All SAEs will be documented in the CRFs. SAEs will be reported to the local IRB per the following guidelines:

Adverse event reports will only be submitted to the local IRB if they are determined by the principal investigator to be: unanticipated, serious, and possibly, probably or definitely related to a research study procedure.

SAEs meeting these criteria (except for deaths) must be reported to the IRB *within 5 working days* of the study team's notification of occurrence. Deaths that are unanticipated and are possibly, probably or definitely related to a research study procedure must be reported to the IRB *within 24 hours* of notification of occurrence. Any relevant follow-up information regarding the SAE should be submitted to the IRB as soon as it becomes available and/or upon request. SAE reports to the IRB must include the following: subject identifier, adverse event or problem description, the event relationship to the test article or underlying condition, seriousness assessment, whether the event was anticipated or unanticipated, type of report (initial or follow-up), date of injury, whether the intervention was stopped, and, if so, whether it was re-started, and whether the event provides new risk information that alters the risk-benefit assessment and/or should be added to the informed consent disclosure.

13.0 STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

Based on our review of MME usage in patients who received QL blocks compared to those who received no blocks, the study will 35 patients per arm (70 patients total) for an alpha of 0.05, beta of 90% and an estimated 10% attrition rate. The total study duration is estimated at 6 months. Recruitment will take place with potential patients coming from a pool of high-volume hernia surgeons. For reference, this group of surgeons performs 600 hernia surgeries per year. We anticipate that approximately 15-20 patients will be randomized per month.

Descriptive and frequency statistics will be used to describe the demographic and clinical characteristics of the sample. The inferential analyses for the trial will be performed in an "intention-to-treat" fashion. MCAR (missing completely at random) analysis will be performed to assess missingness of trial data. If the missingness is random (as per Little's chi-square statistic), then imputation of missing data will be performed using multiple imputation with expectation-maximization. A "per-protocol" analysis will also be performed on the data.

The primary outcome of total MMEs in the first 24 hours after ventral hernia repair between the two treatment arms using either an independent samples t-test (if normality and homogeneity of variance assumptions are met), or a Mann-Whitney U test (if either or both assumptions are violated). Means, standard deviations, mean differences, and 95% confidence intervals (95% CI) of the mean differences will be reported for any t-test analyses, while medians and interquartile ranges will be reported for any Mann-Whitney U tests. The same statistical methods will be performed for the secondary endpoints of aggregated NRS scores post-24 hours, total MMEs after 48 hours, time to return to work (days), hospital length of stay (LOS) after surgery, and PROMIS and HerQLes metrics. For the secondary endpoints that are categorical in nature, either Chi-square or Fisher's Exact test will be performed to compare the treatment arms for perioperative and post-operative complications. The incidence of opioid-related AEs and SAEs will be compared amongst the groups using either chi-square or Fisher's Exact test.

Multiple regression analysis will be performed to control for BMI, baseline opioid use, smoking status, presence of diabetes, and immunosuppression when looking at the association between treatment and MMEs at 24 hours. Separate factorial ANOVAs will be used to look at differences in the primary outcome (MMEs at 24 hours) based on hernia width, hernia location, mesh fixation type, and location of mesh within the abdominal wall. Statistical significance will be assumed at a two-sided alpha value of 0.05. All analyses will be performed Susing SPSS Version 29 (Armonk, NY: IBM Corp.).

14.0 STUDY MANAGEMENT

The PI and study team has the site resources, time availability, and the patient population needed to complete this protocol under GCP guidelines. The PI is ultimately responsible for the conduct of the trial; however, she will delegate authority to appropriate members of the research team. The PI will ensure that the study team will:

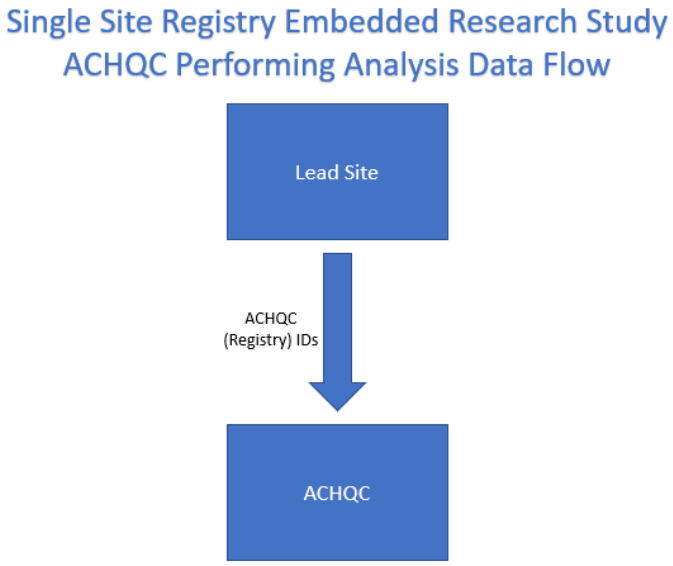
- Comply with GCP and other regulatory requirements.
- Obtain IRB study approval.

- Will allow monitoring and auditing by regulating institutions.
- Ensure delegated personnel study responsibilities are qualified and trained appropriately.
- Ensure that study team members have sufficient time to properly conduct and complete the trial.
- Ensure that all persons assisting with the study are adequately informed about the protocol, the treatments being administered, and their study-related duties and functions.
- Ensure compliance with GCP guidelines regulatory requirements.
- Will maintain a list of research team members and delegated duties.
- Assures protocol compliance.
- Report protocol non-compliance immediately and appropriately.
- Follow regulations and guidelines to protect subject rights, safety, and welfare.
- Assure compliance by all research team members of GCP regulations

15.0 DATA MANAGEMENT

Data will be collected and managed by trained study team members. Data will be stored in a locked cabinet in the coordinators' office with limited access. Data collected during the study will be retained in patients' research records for at least 6 years after the study is completed. At that time, the research information not already in the patients' medical records will be destroyed, per institutional guidelines. The primary investigator is a participant of the Abdominal Core Health Quality Collaborative (ACHQC). The ACHQC is an organization dedicated to quality improvement in hernia and abdominal core health and already receives protected health information from this institution for routine healthcare operations under the terms of a business associate agreement.

ACHQC data from Kaela Blake, MD, which is already a participant of the ACHQC, will be collected for quality improvement purposes via routine healthcare operations per the ACHQC Participant Agreement. This information will be used for the research study as outlined in this protocol. Registry IDs (ACHQC IDs) will be securely transmitted from Kaela Blake, MD to the ACHQC analytic team to identify patients enrolled in the study.



15.1 Data Protection

Throughout the study, measures to ensure the privacy of information on study subjects will be maintained. All project investigators and staff have been trained in human subjects in research and in the new HIPAA regulations. Subjects and staff will be informed of the confidentiality of information and assured that data will be used only for statistical purposes in which the individual cannot be identified. Conversely, no identifiable information on any individual will be released to anyone other than project personnel without a signed medical release from the subject, or where appropriate, the next of kin or a physician in case of a life-threatening emergency to the subject. All project personnel will be instructed not to discuss any cases with persons other than project personnel.

For this specific project, all information related to patients will be identified only by patient initials and study number. However, for research purposes, it may be required to collect PHI such as age, DOB, Medical Record Number and dates of diagnoses. Only the study team will have access to this data, and it will not be shared with anyone outside of the study team. Data will be collected on paper source documents and transcribed into the GSM REDCap system. Only study team members will have access to the database. The database will utilize the study number assigned and will not include the subjects name or MRN. All subjects will have an assigned number. All completed paper forms will be kept in locked files in locked rooms to which only project personnel have access.

15.2 Data and Safety Monitoring

Monitoring will be completed by the GSM Office of Research Support and includes a review of original case records. It will include monitoring to assess patient safety, the consent process, record-keeping, protocol adherence, and data collection. The Investigator will record all protocol

deviations. Unexpected clinically significant adverse events will be reported to the IRB. In general, the investigators will monitor any adverse reaction to the questionnaires and assessments conducted during the study. Any missing data will be omitted from the final statistical analysis.

15.3 Protocol Deviations

A protocol deviation is failure to follow procedures specified in the approved research protocol, which include (but are not limited to), deviations from study inclusion/exclusion criteria, or failure to follow criteria for subject follow-up, withdrawal, or timely monitoring procedures. Protocol deviations will be reported per the UTGSM IRB SOPs.

15.4 Records

15.5.1 Source Documents

Source documents provide evidence for the patient's existence and substantiate the integrity of the data collected. Source documents will be stored and maintained by the study team in a secure location. Data entered in the database that is transcribed from source documents must be consistent with the source documents or the discrepancies must be explained. All electronic data must be derived from source documents.

15.5.2 Direct Access to Source Data and Documents

The PI will permit trial-related monitoring, audits, and regulatory inspection, providing direct access to source data/documents.

15.5.3 Storage of Records

The PI will retain the source documents and essential documents for at least 6 years after the research is completed and the study is closed with the IRB. Records will be kept longer if other requirements apply.

16.0 COMPLETION OF THE STUDY

When the trial is completed, the PI will inform the IRB of the completion in writing.

17.0 REFERENCES

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