PROTOCOL TITLE:

Dermatomal spread of Paravertebral and Erector Spinae Plane nerve blocks as compared by Thermal Imaging.

PRINCIPAL INVESTIGATOR:

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Anesthesiology & Critical Care Medicine

ADMINISTRATIVE CONTACT:

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VERSION NUMBER:

1.

DATE:

March 17, 2021

REGULATORY FRAMEWORK:

Please indicate all that apply (please note that the regulatory framework **does not** mean the funding source):

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

This study is not funded

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

"A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

Table of Contents

1. Objectives

The objective of this study is to use thermal graphic imaging to objectively compare sensory nerve blockade distribution after placement of a Paravertebral peripheral nerve block vs. after placement of an Erector Spinae Plane block. Participants will receive both types of block (one per side), rather than one type on both sides. Both types are generally accepted, in common usage for this patient population, and applied frequently at UNM Outpatient and Imaging Services (OSIS) by investigators. Participants are drawn from a population that would already receive one or the other, depending on provider preference.

1.1. The investigators hypothesize that the two types of block procedures result in comparable anatomical distribution of effectiveness, as determined by thermal imaging.

2. Background

Since the opening of the University of New Mexico Outpatient Day Surgery Center, breast surgery has been accomplished successfully due to regional anesthesia. Before the development of ultrasound imaging, landmark paravertebral regional anesthesia blocks were placed before surgery to provide post-operative analgesia and enable patients to recover from their surgery in the comfort of their homes. As ultrasound imaging technology was developed and became more mainstream, Paravertebral blocks were then placed using a combination of landmark and live ultrasound imaging while placing the blocks. Ultrasound imaging of the spinal column and the vertebral space is complex. Imaging of bone creates artifact and drop out of the ultrasound image, therefore, creating great difficulty in performing this block under ultrasound-guidance. At the same time, using ultrasound imaging to place these blocks, increases patient safety as the pleura of the lung can be imaged and therefore prevent inadvertent puncture of the lung by the block needle. As technology has further developed, resolution of the paravertebral space is improving and in the hands of experienced ultrasound-guided regional anesthesiologists this block can be placed successfully.

The Paravertebral regional block is considered the gold-standard of anesthetizing the spinal nerves of the thorax and abdomen.[i] The block is placed as the spinal nerve root exits the spinal cord and therefore, the somatic and sympathetic parts of the nerve root are anesthetized. Due to the complexity of placing this block, alternative blocks have been sought out that are easier to place and infer better safety for patients. Recently, the Erector Spinae Plane (ESP) block has been introduced as an alternative to the Paravertebral block.[ii] It is easier to place in the inexperienced providers hands, easier to teach to new providers and in patients with difficult anatomy sometimes the only safe image that can be obtained for placing a block. The mechanism of action for the Erector Spinae Plane block has not been fully elucidated. Contrast dye studies in cadavers, show that possibly the local anesthetic spreads to the paravertebral space anesthetizing the dorsal ramus of the spinal nerve root where other research demonstrates local spread in the planes of the intercostal muscles reaching lateral cutaneous nerves.[iii]

Studies comparing the two blocks and their efficacy has had mixed results. It is difficult to objectively measure the blocks distribution and pain control. Asking

patients' their pain level after surgery is one subjective measure used and looking at patients' morphine equivalents is another more objective method employed. In one systematic review done by Huang et al, they discovered that the Erector Spinae Plane block significantly improved postoperative pain scores and decreased opioid consumption as compared to no block and that these results were similar to patients with a Paravertebral Block.[iv] In another study conducted by Turhan et al, using pain scores to assess the blocks' efficacy, they concluded that thoracic Paravertebral blocks were associated with significantly lower pain scores than Erector Spinae Plane blocks for Video-assisted thoracoscopic surgery.[v]

Finding an objective way to map blocking of a peripheral nerve would be an ideal way to compare the efficacy of the two blocks. When we use regional anesthesia for the upper extremity surgery and anesthetizing the brachial plexus, we can objectively assess the success of the block by testing loss of motor function. If the nerve's motor component is affected, we know the sensory component is affected also. Therefore, loss of motor function serves as a surrogate to test loss of sensory function without having to cause pain to test the block. Unfortunately, the thoracic nerves do not have a motor component. The spinal nerve roots contain a somatic component and a sympathetic component. When the sympathetic nervous system is block by regional anesthesia, the blood vessels in the distribution of the block are unable to vasoconstrict and therefore, vasodilated. This vasodilatation leads to an increase in temperature of the skin of the trunk. Being able to measure temperature changes of the skin in the dermatomes of where the block is placed would give us an objective measure to map where the block is blocking nerve signal transmission.

Assessment of temperature change after Paravertebral block placement was first used in 1995 in a case series of six patients presenting for abdominal surgery. At this time, the Paravertebral blocks were placed using a landmark technique and thermal imaging was conducted using technology of the time. These authors used temperature changes as a surrogate marker of sympathetic and somatic nerve blockade.[vi] A case study published in 2014 was specific to using thermal imaging to assess Paravertebral blockade in a patient presenting for breast surgery. Morznski et al. demonstrated this objective mapping of spinal nerve root blockade. He placed a unilateral landmark Paravertebral block and then using an infrared camera documented increases in temperature changes within the dermatomes of the blocked area.[vii]

After a complete review of the literature, there have not been any articles to date that have been published using thermographic imaging to assess the efficacy of Erector Spinae Plane blocks. I purpose using thermographic imaging to assess dermatomal blockade of spinal nerves to compare the efficacy of Paravertebral nerve blocks versus the efficacy of blockade by placing an Erector Spinae Plane block. Based on the outcomes of this case series, further randomized controlled studies could be conducted to statistically compare the two blocks for the best analgesic blockade and if the two blocks are unequivocal this gives providers the ability to choose the safest of the two blocks.

[References are listed at the end of this protocol document]

3. Study Design

This will be an unblinded case series of consenting patients serving as their own controls in a comparison of two commonly accepted nerve blockade techniques.

4. Inclusion and Exclusion Criteria

4.1. Potential participants will be identified from among investigators' usual patient caseload. The inclusion/exclusion criteria are simple, and will not require the recording of any PHI.

4.2. Inclusion criteria: Participants will be drawn from adult female patients having bilateral mastectomy surgery over the age of 18.0 years, who consent to regional anesthesia for their postoperative pain relief. Exclusion criteria: Patients will not be enrolled if they are not yet 18 years old, unable to consent, using anticoagulant medication or have a bleeding disorder, are pregnant (all female patients of childbearing age who present for surgery already receive a urine pregnancy test for non-research reasons), or do not speak English.

4.3. Individuals from these protected groups will not be included in this research:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners.

4.4. Male patients will be excluded. Bilateral mastectomy surgery is rare in this patient group, and any male patients who do present for such surgery are likely to be experiencing a clinical situation that is distinct from the typical bilateral-mastectomy population; potentially even idiopathic. Enrolled male participants may therefore have an untoward effect on the interpretation of study results, and will be excluded for that reason.

4.5. Non-English speakers will be excluded. This is a small unfunded study, and the cost of preparing suitable Spanish-language consent materials would present a substantial burden on the ability of the investigators to proceed. The investigators are not aware of any reason why language preference would affect study results or even correlate with other factors that may affect them, or why results from the contemplated sample could not be reliably extrapolated to patients who speak languages other than English.

5. Number of Subjects

5.1. A maximum of 12 participants will be recruited at this site. The planned case series size is 6 participants for whom complete date are available. The excess enrollment capacity is intended to accommodate any participants for whom the planned regional anesthesia techniques cannot be completed adequately. For example, poor ultrasound imaging or particular specifics of patient anatomy may lead to abandonment of an attempt to place regional anesthesia.

6. Study Timelines

6.1. Describe:

- Individual participants will participate in the study for less than one hour after providing consent, including time for block placement, time for the blocks to take effect, and the thermal imaging.
- The investigators anticipate that all subjects can be enrolled within 12 months.
- Upon the completion of data collection, analysis and manuscript preparation are anticipated to take another five months.

7. Study Endpoints:

7.1. The primary outcome is the dermatomal distribution of skin temperature changes. No secondary outcomes have been identified.

7.2. The use of thermal imaging technology presents minimal risk to patients. In the unexpected event that an excessive number of patients experience block failure (in the opinion of the principal investigator), the investigators will stop enrollment. This is extremely unlikely, as both types of block are in common usage at OSIS with comparable success rates.

7.3. No exploratory endpoints have been identified.

8. Research Setting

8.1. Research activities will occur at the UNM HSC Outpatient Surgery and Imaging Services (OSIS) facility.

8.2. Physician-investigators on the study team will identify potential participants from among their usual patient caseload, using information already available to them. Recruitment will occur in the pre-operative holding areas of OSIS.

8.3. Recruitment, nerve block placement, and thermal imaging will occur in the pre-operative holding areas of OSIS. Post-recruitment analysis will occur in Anesthesiology department offices.

8.4. A community advisory board will not be used.

9. Resources Available

9.1. The PI (Mary Billstrand MD) is a board-certified anesthesiologist at UNM. Her subspeciality area is regional anesthesia, where local anesthetics are used to provide surgical and analgesic pain relief by blocking nerve conduction of painful stimuli. She has supervised or personally place over 10,000 peripheral nerve blocks in her career. She teaches and supervises anesthesiology residents and regional anesthesiology fellows in regional anesthesia. She even teaches at a national course for practicing anesthesiologists to learn regional anesthesia. Dr. Billstrand has been awarded sabbatical time to conduct this study by her department. She is the Medical Director of the Outpatient Surgical Center (OSIS) where the study will take place. She has intimate knowledge of the study site, procedures, and patient population. Dr. Billstrand will be responsible for all

anesthesia-related medical decisionmaking, and ordering and evaluation of any diagnostics or therapeutics that become necessary in context of the research.

9.2. Describe other resources available to conduct the research: For example, as appropriate:

- Approximately two patients per month presents to OSIS for bilateral mastectomy. Therefore, it is feasible that at least 12 patients can be recruited within 12 months.
- Facilities at OSIS are designed to accommodate regional-anesthesia procedures, which are a standard of care for bilateral mastectomies performed there.
- The Department of Anesthesiology has a thermal imaging camera (FLIR E95 42).
- OSIS has the facilities, supplies, personnel, and equipment necessary to respond to any situations arising from regional anesthesia procedures and mastectomy surgery.
- The PI will obtain all subjects' informed consent, perform their regional anesthesia procedures, and acquire thermal imaging. There is a small subset of regional anesthesiologists (approximately 6 attending physicians and 2 fellows) as well as midlevel, nursing, and resident physicians who will assist the PI in anesthesia-related matters outside the research, as in usual practice. While not performing research procedures per se, they will be made familiar with the research and its protocol-specified procedures.

10. Prior Approvals

10.1. The Departmental Review Form is included with this application.

11. Multi-Site Research

11.1. NA.

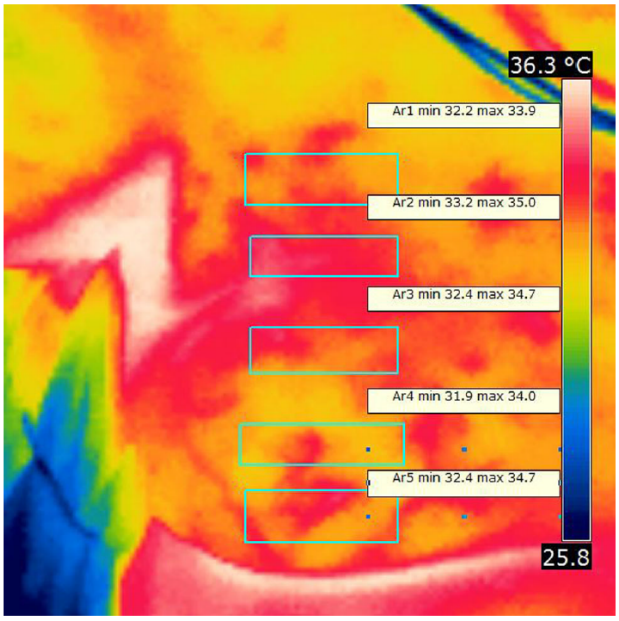
12. Study Procedures

12.1. Nearly all procedures described below are routine and within standard of care (SOC), with two exceptions performed for research purposes: the use of thermal imaging to evaluate nerve block distribution, and the application of different nerve block techniques (Erector Spinae Plane block on one side, and paravertebral block on the contralateral side) in the same patient. All participants are drawn from a population who would receive two blocks with the same technique, typically one of these two, regardless of the existence of this research project.

12.2. Bilateral mastectomy patients will be identified before surgery. Informed consent will be obtained. In the preoperative holding area at OSIS, patient will be positioned in sitting position and a universal time-out will be performed. Patient will have surgical site marking by surgeon and regional site marking by regional anesthesiologist. The PI will randomly draw from a jar the side of the patient that the Paravertebral block will be placed on and the side that the Erector Spinae Plane block will be placed on. Patient will be administered sedation via IV for

the procedure. Thermal imaging photographs will be obtained using the Flir E95 thermal imaging camera of the posterior, lateral and anterior thorax. The first of three sets of images will be obtained before regional anesthesia (nerve block) placement. Regional anesthesia will be performed as in usual practice for this patient population. The specifics of the block placement will not be modified from our usual practice for purposes of this research project. The patient will receive a Paravertebral block at T4 on one side and an Erector Spinae Plane block at T4 on the contralateral side under ultrasound guidance. Twenty minutes after the blocks are completed, thermal imaging photographs will be obtained of the posterior, lateral and anterior thorax. Ten minutes later another set of thermal imaging photographs will be obtained. The patient will then proceed to surgery. Ultrasound images are all saved under patient's MR per standard of care. Thermographic images will be saved on secure HSC servers under a sequential participant number for later review and analysis.

An example of the thermal image (from reference vii) is provided below:



13. Data Analysis

13.1. As this is a case series, formal statistical analysis beyond routine descriptive statistics is not appropriate.

13.2. As this is a case series, a power analysis is not appropriate.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

The investigators believe that this is a Minimal Risk study, because enrolled patients would be offered regional anesthesia regardless of the existence of this study, there is not a substantial known difference in the success rates of the two regional-anesthesia techniques to be compared, the thermal imaging will not include patient identification, and there will be no deviation from standard procedures for Paravertebral and ESP block placement.

15. Withdrawal of Subjects

15.1. Sometimes due to subject's anatomy a clear ultrasound image cannot be obtained and therefore a regional anesthetic cannot be safely administered. When this occurs, the patient will no longer be a candidate for the study and will be withdrawn. The subject's preblock thermal imaging will be deleted.

15.2. All other aspects of care will proceed as if the research did not exist, including accommodation for patients whose blocks cannot be performed.

15.3. Any patient who wishes to withdraw will be allowed to do so. The investigators do not anticipate any patient insubordination issues as to research procedures, but any uncooperative patients will be removed from participation and surgery will proceed as normal depending on surgeon preference. Similarly, any participants would be withdrawn if investigators conclude for any reason that their participation presents more risk than benefit.

15.4. If a subject withdraws or is withdrawn after thermal imaging is recorded, that subject's thermal images will be deleted.

16. Data Management/Confidentiality

16.1. No data will be shared with any external entity, except as required by law.

16.2. The research team includes physicians treating prospective and consented participants as patients in the course of their usual job duties, so access to PHI for these patients already exists and is routine.

16.3. The research requires access to identifiers and PHI for inclusion screening and demographic purposes. The data to be used are not publicly available. The only element of the data that may be considered "sensitive" is the thermal imaging of the anterior thorax (chest) area of consenting participants. The thermal images do not resemble common photographs, but nonetheless necessarily include representations of adult women's breasts (see example in section 12). Other types of potentially sensitive data will not be sought or recorded.

16.4. Zip codes will not be recorded for research purposes.

16.5. The investigators do not plan to seek or obtain a Certificate of Confidentiality from the NIH.

16.6. Data will be secured by the use of electronic file storage on HSC secure servers, which are password-protected and feature numerous other security measures.

16.7. Data will be coded by sequential participant number.

16.8. The data to be collected are relatively minimal and the sample size is small, so quality control is not anticipated to be an issue. However, the linking sheet to MRN will permit any missing or unclear data to be checked and corrected as appropriate.

16.9. Describe the following:

- The data will include the thermal images and basic demographic data: age, BMI, and surgical procedure.
- Data will be stored in electronic format on secure HSC servers.
- Data will be collected electronically from the FLIR camera and entered electronically in files stored on secure HSC servers.
- Data will be stored for 6 years, as with all other study documentation.
- Only the PI and study team members will have access to the data and study documentation, except as provided by law and HSC policy.

16.10. The main set of data (the thermal images) will be temporarily stored on the FLIR camera, before being transferred to a folder on the secure HSC network and deleted from the camera. The camera itself will be securely stored in a locked cabinet in Anesthesiology department offices.

16.11. Audio and video recordings will not be made or used.

16.12. Data will include thermal-imaging photographs, which will not include the facial area. These photographs use false color to depict skin surface temperature, and as such are different from typical photographs. Participants will be offered a look at the recorded images. Images will be deleted on participant request, and the participant will then be excluded from the study.

16.13. The research record will be maintained for at least 6 years after study completion.

16.14. Research records for this study will not involve minors, as they are excluded from participation.

17. Data and Specimen Banking

17.1. Data will not be banked for future use.

18. Risks to Subjects

18.1. Both of the regional anesthesia techniques under evaluation in this study are part of routine practice at UNM OSIS. The research does not modify any element of patient selection for regional anesthesia or details of placement. The only research-specific procedures are the use of two regional anesthesia techniques (rather than one) on consenting patients, and the recording of thermal imaging.

18.2. Peripheral nerve blocks like the ones used in this research are necessarily restricted to one side of the body and must be performed bilaterally for bilateral anesthesia. Therefore, some degree of risk of asymmetry in anesthesia effectiveness already exists regardless of the existence of this study. For that reason, it is difficult to evaluate the extent to which any risk of anesthesia asymmetry may be increased by this research, but it may exist; meaning that there is some small chance that a patient could have less pain control on one side. As noted in the consent, previously unknown risks or side effects also

cannot be ruled out, but both techniques are well studied, so this is very unlikely.

18.3. The thermal images do not resemble normal photographs, but patients may experience unease while they are taken.

18.4. The only other risk identified by the investigators is that of breach of confidentiality, which exists in all research.

18.5. Both of the regional anesthetic techniques are well established with known safety profiles. Similarly, thermal imaging carries no known inherent risks. Therefore, it is unlikely that this research would carry any unforeseeable risks.

18.6. All female patients of childbearing age at OSIS receive urine pregnancy tests prior to surgery. Pregnant patients will be excluded, and the effects of regional anesthesia wear off within hours, so the investigators do not anticipate any risks posed to an embryo or fetus by this research.

18.7. The investigators do not anticipate any risks posed to others not participating in the research.

18.8. The investigators have taken several steps to reduce or mitigate the probability and severity of risks. These include, but are not limited to, 1) the use of routine regional anesthetic procedures and anesthetic dosages without research-specific modifications, 2) the exclusion of pregnant patients, 3) the use of minimal data to support this case series, 4) the routine availability of alternative pain relief methods (general anesthesia, intravenous analgesic medications, non-steroidal anti-inflammatory drugs, longer-acting oral pain medications, etc.) in any case of block failure, 5) the selection of established regional-anesthetic techniques to compare, 6) the availability of the full complement of personnel, supplies, and equipment to respond to any emergency, 7) the use of UNM HSC's secure servers, locked cabinets, etc. to store data securely.

19. Potential Benefits to Subjects

19.1. Participants are drawn from a population that is already offered regional anesthesia for pain control, so there is no direct benefit from participation in this study.

20. Recruitment Methods

20.1. Patients having bilateral mastectomy procedures performed by UNM HSC surgeon Dr. Sangeetha Prabhakaran will be referred to the PI for recruitment to the study.

Recruitment materials will not be used, other than the consent document.

21. Provisions to Protect the Privacy Interests of Subjects

21.1. All study procedures will occur with a physician-investigator who is already interacting with prospective and consented patients as part of their routine job duties. These procedures will occur in the pre-operative holding area, which is already sufficiently private for confidential doctor-patient conversations and medical procedures to occur. The thermal imaging involves body areas that are

already exposed and discussed in the context of the medical treatment that constitutes part of the inclusion criteria.

22. Economic Burden to Subjects

The two types of regional anesthesia will be paid for by participants or third-party payers. Both of them are part of routine and standard care at UNM OSIS. The costs associated with the two regional anesthesia techniques are the same, so participant costs would not be affected by participation in this study.

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
Thermal imaging	All	☒	☐
_____	_____	☐	☐
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Surgery, medications, professional services	All	☐	☒
Anesthesia	All	☐	☒

22.1. Participation carries no other known costs.

22.2. Adverse events attributable to the research are not anticipated, but if any occur, costs for their treatment would be paid by patients and/or third-party payers. This is the same as for similar nonparticipants.

23. Compensation

23.1. Participants will not be compensated for their participation.

24. Compensation for Research-Related Injury

24.1. As the only research procedures are the use of thermal imaging and the use of two accepted regional-anesthesia techniques (all participants would receive one or the other of them regardless of the existence of this research), the investigators do not anticipate any research-related injuries and therefore do not anticipate any costs related to them.

25. Consent Process

25.1. Written consent will be obtained from all participants.

25.1.1. A study-team member (usually the PI) will obtain consent. All study team members have HSC-mandated HIPAA and HITECH training, as well as CITI human-subjects and COI certifications.

25.1.2. The consent process will occur immediately after recruitment, in the private pre-operative holding areas at OSIS.

25.1.3. All prospective participants will be assured that participation has no effect on the care received. For example, all nonparticipants are still candidates for regional anesthesia as in usual practice.

25.1.4. The time available for prospective participants to consider their participation is the same as that in which they consider whether to receive regional anesthesia at all, and this study does not appreciably modify risks beyond confidentiality breach. For those reasons, the investigators believe a suitable amount of time is available for patients to consider participation.

25.1.5. The study procedures are brief, so the investigators do not anticipate any issues with ongoing consent. However, any participants who request deletion of the recorded thermal images will be assumed to have withdrawn consent, and their wishes will govern.

25.1.6. Investigators will use routine methods to ensure participant understanding, such as teachback, invitation for the patient to ask questions, and careful attention to the context and content of those questions.

Subjects not fluent in English

25.1.7. NA; subjects who prefer to speak a language other than English will not be enrolled.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

25.1.8. NA; these participants will not be enrolled.

Subjects who are not yet adults (infants, children, teenagers)

25.1.9. NA.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

- NA

26. Documentation of Consent

26.1. A written consent document will be used.

27. Study Test Results/Incidental Findings

27.1. **Individual Results:** The investigators do not plan to routinely share any individual results with participants. The research does not involve any laboratory results or other findings that would carry clinical significance beyond the temporary effects of the regional anesthesia.

27.2. **Incidental Findings:** Incidental findings are not anticipated in this research.

28. Sharing Study Progress or Results with Subjects

28.1. The investigators do not plan to share study progress or overall study results with subjects. Others' experiences with the regional anesthesia are not directly relevant to individual patients.

29. Inclusion of Vulnerable Populations

29.1. NA; this research does not include any of the populations generally viewed as vulnerable.

30. Community-Based Participatory Research

NA.

31. Research Involving American Indian/Native Populations

31.1. While this study may incidentally enroll some Native American participants, it does not specifically target them for inclusion or exclusion, or seek to draw conclusions about Native Americans as a group.

32. Transnational Research

32.1. NA

33. Drugs or Devices

33.1. The research does not modify the selection, dosage, or administration of any medications from usual practice. The only modification from usual practice is the use of two accepted regional-anesthesia techniques rather than one or the other used bilaterally.

33.2. The study involves the use of a FLIR E95 thermal imaging camera as a means of recording data, in accordance with its usage instructions.

33.3. No investigational (IND) drugs will be used in this study.

34. Principal Investigator's Assurance

By submitting this study in the Huron IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is to be directly entered onto a data collection form that is stored in a secured access folder on HSC central IT managed network storage (such as the N:\Research-Studies drive), or in a secure HSC Information Security approved system such as REDCap.
2. **Temporary storage -- de-identified data collection**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be

temporarily stored using encrypted removable (e.g. CD-ROM (a compact disc used as a read-only optical memory device for a computer system), USB flash/thumb drive (a small external flash drive that can be used with any computer that has a USB port), etc.) media or a university owned electronic storage device or hard copy document. This temporarily stored data must be transferred to HSC central IT managed network storage and deleted from the temporary device as soon as possible. **The important security safeguard is that no identifiers be included if the data is entered or stored using a storage container that is not managed by HSC central IT.**

3. **Permanent (during data analysis, after study closure) storage** must reside on HSC central IT managed network storage (such as the N:\Research-Studies Drive). Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted or unsecure storage devices/computers (an example of an unapproved storage location would be storing the data locally on your HSC computer hard drive rather than on the HSC network drives). Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

35.CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36.Partial Waiver of Consent for Screening/Recruitment

NA; the screening review is preparatory to research.

37.Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

☐ Yes. Describe:

☒ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☒ True

☐ False

38.Waiver of Documentation of Consent

NA.

39.Alteration of Consent

NA.

40.Full Waiver of Consent/Parental Permission

NA.

41.Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)

NA.

42.Full Waiver of HIPAA Authorization (Checklist)

NA.

43. Other Waiver Types (Checklist)

NA.

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44. Vulnerable Populations (Checklist)

NA.

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45. Medical Devices (Checklist)

NA. While the research involves the use of a thermal imaging camera, it does not evaluate the camera itself, its functionality, or its safety or effectiveness.

46. Export Control (Checklist)

NA.

Data Transfer/Sharing/Storage (Checklist) (required –do not delete even if the answer is "No")

Data Use Agreement (DUA) Contacts:

Sponsored Projects Office

- Aida Andujo, Manager, AAndujo@salud.unm.edu
- Siiri Wilson, Contract Specialist, SiWilson@salud.unm.edu

Privacy Office

- Laura Putz, Privacy Officer, LPutz@salud.unm.edu
- Gayle Shipp, Privacy Specialist, GShipp@salud.unm.edu

Information Security Office

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Provide all information requested if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will UNM data be transferred/shared with an external entity (i.e. another institution, company, etc.) or will an external entity's data be transferred/shared with UNM?

☐Yes. **If yes, all questions must be answered congruently based on protocol provisions.**

☒ No. **If no, the remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing:
C. Provide the name of the entity(s) that data will be transferred/shared with, if incoming:
D. Provide the name of the entity(s) that data will be transferred/shared with, if outgoing:

E. Provide the external entity(s) contact name, email and phone number with whom the data agreement is going to be executed. List contact information for each external entity(s) that are involved with the project.

Contact Name	External Entity	Email	Phone Number

F. Who is responsible for transmission of the data?
G. Who is responsible for receiving the data?
H. Describe how the data will be securely transmitted/shared . Please note data cannot be transmitted/shared without assistance from UNM HSC Central IT. **RequestHSC Central IT Transfer from the ISO office. (cannot transfer via email, cloud storage services such as DropBox OneDrive, and fax)**

I. For data being transferred/shared with outside locations or entities, describe the following:

1. Where will data be stored and how will it be protected? (i.e. encryption, password protection, access controls, use ofREDCap, etc)?
    - *If REDCap, who manages/owns REDCap (i.e. UNM HSC or other external entity)?*
    - *If REDCap or other external system is not UNM HSC REDCap managed/owned, please provide the name of owner and the access (login) link?*

        Provide IT security point of contact for externally managed/owned REDCap:
2. What is the method being used for data collection and storage (i.e. electronic, hard copy, etc)?
3. How long will the data be stored.Must be congruent with sections 16.16-16.18)?
4. Where will data be stored (UNM HSC requires that research data be stored on the N:\Research-Studies drive managed by HSC Central IT)?
5. Who will have access to data?

J. Please list all specific data elements, variables, etc. to be sent out (outgoing) and/or received (incoming).

What data is incoming?
What data is outgoing?

K. What is the classification of the data (de-identified, limited data set, protected health information, other)? See below for definitions:
DE-IDENTIFIED DATA: Identifiers That Must Be Removed to Make Health Information De-Identified:

(i) The following 18 identifiers must be removed of the individual or of relatives, employers or household members of the individual must be removed: (A) Names; (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; ***and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;*** (D) Telephone numbers; (E) Fax numbers; (F) Electronic mail addresses; (G) Social security numbers; (H) Medical record numbers; (I) Health plan beneficiary numbers; (J) Account numbers; (K) Certificate/license numbers;(L) Vehicle identifiers and serial numbers, including license plate numbers; (M) Device identifiers and serial numbers; (N) Web Universal Resource Locators (URLs); (O) Internet Protocol (IP) address numbers; (P) Biometric identifiers, including finger and voice prints; (Q) Full face photographic images and any comparable images; and (R) Any other unique identifying number, characteristic, or code; and (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

LIMITED DATA SET: A "limited data set" is a limited set of identifiable patient information as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (HIPAA). A "limited data set" is information from which "facial" identifiers have been removed. A "limited data set" is information from which "facial" identifiers have been removed. Specifically, as it relates to the individual or his or her relatives, employers or household members, all the following identifiers must be removed in order for health information to be a "limited data set": names; street addresses (other than town, city, state and zip code); telephone numbers; fax numbers; e-mail addresses; Social Security numbers; medical records numbers; health plan beneficiary numbers; account numbers; certificate license numbers; vehicle identifiers and serial numbers, including license plates; device identifiers and serial numbers; URLs; IP address numbers; biometric identifiers (including finger and voice prints); and full face photos (or comparable images).

The health information that may remain in the information disclosed includes: dates such as admission, discharge, service, DOB, DOD;
city, state, five digit or more zip code; and
ages in years, months or days or hours.

It is important to note that this information is still protected health information or "PHI" under HIPAA. As a limited data set the information is still subject to the requirements of the federal and state privacy and security regulations.

PROTECTED HEALTH INFORMATION (PHI): PHI is defined as any individually identifiable health information collected or created as a consequence of the provision of health care by a covered entity, in any form, including verbal communications. PHI is

information that can be linked to a particular person and that is created, used, or disclosed in the course of providing a health care service (i.e., diagnosis or treatment). There are 18 PHI identifiers as listed in the de-identified data definition section.

L. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information? ☐Yes ☐No

If yes, please provide details regarding the consent process:

a. ***Or*** is HIPAA authorization altered or waived? ☐Yes☐No

If yes, please provide details:

M. Does the request to transfer/share data include clinical data that belongs to the UNM Health System? If data originates from the UNM Health System medical records, this question should be answered yes. ☐Yes ☐No

N. Does the data to be transferred/shared include information about patients seen at an external health system or at a third party medical provider? ☐Yes ☐No
If yes, please provide details:

O. Is the external entity a "covered entity"? HIPAA-covered entities include health care providers (i.e. hospitals, doctors, academic health centers), health plans, and clearinghouses: ☐Yes ☐No

P. Is the data that is going to be transferred/shared owned or partially owned by another party? ☐Yes ☐No
If yes, please provide details:

Q. Does the data have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)? ☐Yes ☐No
If yes, please provide details:

R. Is the data publicly available? ☐Yes ☐No
If yes, please provide details:

S. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health ? ☐Yes ☐No
If yes, please provide details:

47. Specimen Transfer/Sharing (Checklist) (required –do not delete even if the answer is "No")

Provide all requested information if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes. **If yes, all questions must be answered congruently based on protocol provisions.**

☒No. **If no, the remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

   1. *Where is specimen storage and how will it be maintained in a secure manner?*
   2. *What is method in which specimens will be collected and stored?*
   3. *How long will the specimens be stored?*
   4. *Who will have access to the specimens?*

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[iv] Huang W, Wenyan W, Weidang X, et al. Erector spinae plane block for postoperative analgesia in breast and thoracic surgery: a systematic review and meta-analysis. J Clin Anesth 66 (2020) 109900

[v] Turhan O, Sivrikoz N, Sungur Z, et al. Thoracic paravertebral block achieves better pain control than erector spinae plane block and intercostal nerve block in thoracospic surgery: a randomized study. J Cardiothorac Vasc Anesth 00(2020)1-8

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