Title of Project: Erector spinae plane block (ESPB); A new technique for perioperative pain control in patients undergoing surgery through a flank or anterior subcostal incision.

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CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Erector spinae plane block (ESPB); A new technique for perioperative pain control in patients undergoing surgery through a flank or anterior subcostal incision.

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-5930. 24 Hour Contact Info: 717-531-8521 and ask for the Urology Doctor On Call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

We are asking you to be in this research because you are undergoing general anesthesia for open kidney surgery, and are between the ages of 18-85 years old.

This research is being done to compare pain scores and use of pain medications following surgery between two groups of patients. One group of patients will receive an Erector Spinae Plane (ESP) block using a local anesthetic (ropivacaine) and routine pain management. The other group of patients will receive an Erector Spinae Plane (ESP) procedure with sterile salt solution (no active local anesthetic) and routine pain management.

The Erector Spinae Plane (ESP) block is a technique in which a local anesthetic is injected within the space between two muscles in the low back in order to reduce pain during surgery.

Approximately 40 people will take part in this research study at Hershey Medical Center.

2. What will happen in this research study?

If you participate in this study you will be randomly assigned to receive one of two study treatments. This means whichever study treatment you receive will be determined purely by chance. You will have an equal chance of being assigned to either of the two study treatment groups. One study treatment group will receive an ESP block with 0.5% ropivacaine (active local anesthetic medication) and routine pain management following surgery. The other group will receive an ESP procedure with a salt solution (no active local anesthetic medication) and routine pain management following surgery. Neither you nor the research team will know which study treatment you are receiving, but the research team will be able to get this information quickly if it is needed to ensure your safety.

Day 1-Screening and Consent
If you decide to join this study, you will be asked to sign this consent form. At your clinic visit before your surgery, the study doctor and research staff will review your medical record to check that you are suitable for this study.

Working Day Prior to Surgery
A member of the research team will call you to ensure that you are planning on coming in for your scheduled surgery (i.e.: not sick, running a fever, has transportation). Members of the research team who will perform the block will be notified to confirm coordination of this procedure in the Same Day Unit (SDU).
You will then be randomized into two groups by the study statistician using a computer-generated randomization list:

- Group 1 – Subjects will receive an ESP block with 0.5% ropivacaine (active local anesthetic medication) and routine pain management following surgery
- Group 2 – Subjects will receive an ESP procedure with a salt solution (no active local anesthetic medication) and routine pain management following surgery

Day of Surgery- Pre-op
In the Surgical Day Unit (SDU), you will receive a study bracelet with the study ID and your specific randomization ID. The block procedure will be performed in the SDU by a member of the anesthesia block team, who is also part of the research team. The placement of the erector spinae catheter will occur according to standard practice guidelines using strict sterile conditions and is similar regardless of type of study medication that you will be randomly receiving. After the block catheter is placed, a member of the research team will pick up the study drug from the pharmacy, deliver it to the SDU and ensure the correct coordination of study drug to you using your study ID bracelet.

Day of Surgery- Operating Room
Once in the operating room, general anesthesia will be induced according to the standard of care for you and your surgery. Intraoperatively, anesthesia is required to use only Fentanyl, a short acting opioid, for additional pain control and requested to refrain from using hydromorphone or morphine. At the completion of the case, Ondansetron will be administered for postoperative nausea. Dexamethasone will not be routinely administered as this can also have analgesic effects. All medications administered by the anesthesia team during the operative case will be recorded in the anesthesia record and reviewed and documented by a member of the research team.

Postoperative Hospital Stay

As per standard of care, you will be taken to the post anesthesia care unit (PACU). Here, the ESPB pump will be delivering the automatic boluses of study drug (15ml every 3 hours) and additionally allow you to self-administer an on demand dose of study drug (0.2% Ropivacaine vs. normal saline) 5ml every 30 minutes. In the PACU, if you have additional pain requirements beyond your previously determined acceptable pain score (asked pre-operatively per hospital standard) the PACU team may start a patient controlled analgesia (PCA) pump. A PCA pump is a device that will deliver a dose of pain medication, in this case hydromorphone, when the demand button is pressed. You may press the demand button whenever you are experiencing unacceptable pain. Additional pain medication may be administered outside of the PCA pump as needed at the direction of your doctors to control your pain. One gram of acetaminophen IV every 8hrs will also be started in the PACU and continued through your hospital stay. Acetaminophen will be converted over to oral regimen on Postoperative Day 1 (POD 1). While on the inpatient wards, additional pain control adjuncts will be provided using oral oxycodone 5-10mg every 4 hours administered based on a pain scale: pain 3-6 translates to 5mg tab and pain 7-10 translates to a 10mg tab. The PCA, as outlined above, may be started later in the hospital course, if needed, based on the patient's needs. If your pain is not controlled after these steps you will be withdrawn from the study and your doctor will discuss further treatment as part of standard of care.

The ESP block will be discontinued at between 6AM-9AM on POD 3. All medications and dosages administered during the hospital stay (PACU and inpatient ward) will be reviewed and documented by a member of the research team to tabulate the total IV and oral opioid as well as study drug requirement of all study patients. Daily pain scales using the Visual analogue scale (VAS) 0-10 will be provided to you by a member of the research team, each morning between 9AM-12PM, on POD 1, 2 and 3 (scale attached). Additionally, on POD 1, between 9AM-12PM, a brief patient satisfaction survey (which has been previously validated (11)) will be provided to you to complete by a member of the research team (document attached). On day of discharge, the same brief patient satisfaction survey will be provided again for you to complete prior to leaving the hospital. You will be provided with a standard home pain regimen which will include use of acetaminophen 500mg oral tabs every 6 hours as needed, oxycodone 5mg oral tabs every 4 hours as needed with a quantity of 30 tabs dispensed.

Postoperative Telephone Visit
Due to the COVID pandemic, a member of the research team will perform the 14-day postoperative visit with you by telephone. During this visit the study team member will determine and document the number of oxycodone tablets you have remaining out of the 30 tabs dispensed. Additionally, this member of the research team will also have you fill out the same brief patient satisfaction survey (document attached). It is at this time that your participation in this study will be concluded.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Following the instructions of the study doctor and the study staff
- Completing questionnaires and satisfaction surveys based on your experience

3. What are the risks and possible discomforts from being in this research study?

Risks specific to this study include:

- Risk of randomization - patient will be assigned to a treatment program by chance. The treatment received may prove to be less effective than the other research treatment(s) or other available treatments.
- Loss of confidentiality associated with being part of a research study collecting personal health information.
- Complications of ESPB: local swelling of clotted blood within the tissues, local infection, collapsed lung, side effects resulting from high levels of local anesthetic in the blood usually resulting in symptoms such as changes in blood pressure, weakness or headache.
- Adverse effects related to the study medications at proposed dosing are uncommon. Most adverse effects noted were at higher dosing; there is limited literature noting adverse effects at proposed dosing.
- Risks of ropivacaine include:
    - Incidence 5% or greater- High blood pressure, nausea, vomiting, fever, headache, back pain, low blood pressure and slow heart beat
    - Incidence 1% to 5%- Urinary retention, dizziness, shaking or exaggerated shivering, rapid heartbeat, anxiety, production of abnormally small amounts of urine, reduced sense of touch or sensation, chest pain, deficiency of potassium in the bloodstream
    - There is also a rare risk of a severe allergic reaction

The care that you receive both pre-operatively and post-operatively will not differ based on the pain block that you receive; however, if your post-operative pain scores are beyond your previously determined acceptable pain score, you may receive additional doses of medication for pain management.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include improved pain control, return of bowel function, less nausea/vomiting, less sedation, fewer side effects from opiates, and decreased length of hospital stay.

4b. What are the possible benefits to others?

The results of this research will provide data that may potentially create improved pain management protocols in patients undergoing general anesthesia for open nephrectomy, and may help to revise and improve the standard of care.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Be part of a different research study, if one is available.
- Not be in this study and receive standard of care for pain management.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

6. How long will I take part in this research study?

If you agree to take part in this study, it will take you approximately 20-30 minutes to complete the given questionnaires and satisfaction surveys. You will remain in the study until your postoperative visit, occurring within 14 days of discharge from the hospital.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include the following identifiers: your name, date of birth, medical record number, and a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Aminsharifi's office.
    - Your research records will be labeled with your code number and will be kept in a safe area in Dr. Aminsharifi's research office and retained for six years.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office

- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- The HMC/PSU pharmacy
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- A group that oversees the data (study information) and safety of this research
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The ropivacaine and salt solution will be provided at no cost to you while you take part in this study
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.

- The research-related tests and procedures that will be provided at no cost to you include: the ESP block procedure and surveys completed as part of this study.

For costs of medical services for care you would receive even if you were not in this research study:

- The costs of the pain medications that are part of the standard of care will be the responsibility of the subject or their insurance company.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment.

<u>HMC/PSU compensation for injury</u>

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

The institution and investigators are receiving funds from the Department of Surgery to support this research study.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Your research doctor may take you out of the research study without your permission.

- A possible reason for this is if continuing the research would be harmful.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

If you stop being in the research study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Aminsharifi at 717-531-5930, for 24-hour assistance you may call 717-531-8521 and ask for Urology Doctor On Call if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name