UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Efficacy of the Erector Spinae Plane Block for Gastrointestinal Malignancy Pain
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Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to reduce abdominal pain for patients with cancer in their gastrointestinal tract.

If you agree to join the study, you will be asked to complete the following research procedures: you will be asked to rate your pain level immediately before and 30 minutes after receiving a nerve block for your pain. 24 hours after the nerve block procedure you will be called to take a short (<5 minutes) survey about your pain levels during the 24 hours after receiving the injection and your satisfaction with the care you received. You will also be asked to provide permission for us to collect your total length of stay in the emergency department and hospital, as well as the type and strength of opioids you receive while in the emergency department and in the hospital.

Your participation will last until the survey is complete 24 hours after receiving your injection.

While there may be no benefit to you, the potential benefit of providing your pain levels, answering a brief (<5 minute) survey at 24 hours, and allowing us to collect data on your length of stay and opioid use here in the emergency department and in the hospital is

that other patients who have gastrointestinal cancer may one day benefit from receiving this procedure.

The alternative to participating in this study is to receive normal care for your abdominal pain.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you are having abdominal pain from your cancer in your abdomen.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form. You will receive a copy of this consent form.

What is the purpose of this research study?

The purpose of this study is to determine if the erector spinae plane block can improve abdominal pain for patients suffering from cancer in their abdomen.

How long will I be in the study?

Your enrollment in the study will last for 24 hours, and will end with a short survey detailing your pain levels over the previous 24 hours. We will be recruiting patients for this study for approximately 12 months. We plan to recruit 25 patients for this study, all through the emergency departments at the University of Pennsylvania.

What am I being asked to do?

You are being asked to provide your pain levels before and 30 minutes after receiving the erector spinae plane block. You are also being asked to fill a short (<5 minutes) survey at 24 hours after you receive the erector spinae plane block. You are also being asked to give our research team to collect the following specific information about your emergency department and hospital visit today: length of stay and total opioid use.

Your phone number will be shared with the Clinical Research Coordinator, Umar Aulia, so that he can call you at 30 minutes and at 24 hours after you receive the erector spinae plane block to administer a short survey about your pain levels.

What are the possible risks or discomforts?
There are no medical risks or discomforts associated with taking part in this study. While there is a risk of breach of confidentiality, we plan to keep all participants' information in a password-protected file. Only physicians and study members with access to this file will be able to view your information.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
You may not get any benefit from being in this research study. However, you may also feel much better after receiving the erector spinae plane block. Furthermore, there are benefits to society as a whole. By reporting positive outcomes of this study, other people with gastroparesis may benefit from the erector spinae plane block.

What other choices do I have if I do not participate?
If you choose not to participate in this study, you can still be treated with the pain medications which you would have normally received for your abdominal pain in the emergency department.

Will I be paid for being in this study?
You will not be paid for being in this study.

Will I have to pay for anything?
There are no costs to you for participating in this study.

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

When is the Study over? Can I leave the Study before it ends?
This study is expected to end after all participants have received the erector spinae plane block, have answered the 24-hour pain survey, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

The confidentiality of your information will be protected in the following way during the study: all information will be coded, stored in a secured, password-protected program called REDcap, access to which will only be available to the members of the study.

Will information about this study be available to the public?

A description of this clinical trial will be available on 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.

What may happen to my information collected on this study?

Future Use of Data

Your information will be de-identified prior to storage for future use. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study. If you change your mind, we will not be able to destroy or withdraw your information that were shared because all identifiers would have already been removed.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a participant, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM). All data collected in this study will be data which you will provide, such as how you are feeling after receiving the erector spinae plane block.

Will I receive the results of research testing that may be relevant to my health?

Results that may be relevant to your healthcare may be released to you. Any results relevant to your healthcare will be released in the EMR through Penn Medicine's patient portal.

What information about me may be collected, used or shared with others?

Your phone number will be shared with the Clinical Research Coordinator, Umar Aulia, so that he can call you at 30 minutes and at 24 hours after you receive the erector spinae plane block to administer a short survey about your pain levels. Your age in years, sex assigned at birth, your gender, your personal medical history, and results from physical examinations and tests (such as CT scans and MRI scans) will be used for the purposes of this study. Your length of stay in the emergency department and in the hospital, as well as the opioids you are administed while in the emergency department and in the hospital, will be recorded. However, this information will not be shared in a manner which will make you identifiable. **Your social security number, home address, and date of birth will <u>not</u> be collected or shared with others.**

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

Nobody outside of Penn Medicine will receive any of your information. No entities outside of the U.S. Office of Human Research (OHRP) will have oversight of this research.

<u>Oversight organizations</u>

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.	.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Participant **[print]**	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date