RUTGERS
Robert Wood Johnson
Medical School

CONSENT TO TAKE PART IN A RESEARCH STUDY
Randomized Control Trial to Assess the Efficacy of Preoperative Erector Spinae Blocks on Cardiac Surgery Postoperative Outcomes
Protocol # 2022001580

Primary Investigator:
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STUDY SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to compare Ultrasound-Guided Erector Spinae Plane (ESP) Blocks using Exparel® (bupivacaine liposome injectable suspension) to Marcaine® (bupivacaine hydrochloride) for pain management and outcomes after cardiac surgery.

Your **time in the study will be** approximately 4 weeks. If you take part in the research, you will be randomized (like flipping a coin) to receive either Exparel or Marcaine for pain control during your cardiac surgery. Data will be collected from your hospital records, and you will complete 2 short questionnaires (5 minutes/each).

These risks are similar to those of standard care and are detailed below. This study is being done for research purposes only and does not offer any treatment.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked

to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Leonard Lee *(*Principal Investigator of this research study) has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Lee may be reached at the contact information listed on top of page one.

Dr. Leonard Lee or another study doctor or nurse will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
During cardiac surgery at RWJUH the doctors use a technique called "Plane Block" to control pain during and after the procedure. This study is comparing two different pain medications to determine if one is better than the other. Both medications are approved by the Food and Drug Administration (FDA) for this indication.

Pacira Pharmaceuticals, Inc, Exparel manufacturer, is providing funds to cover costs associated with performing this study.
Who may take part in this study and who may not?
Patients undergoing cardiac surgery that involves either a small incision (Mini) or larger chest incision (Open).

Patients currently taking pain medications are not eligible for this study.

Why have I been asked to take part in this study?
You are being asked to participate because you are scheduled for either a Mini or Open cardiac procedure.

How long will the study take and how many subjects will take part?
This study is only being done at RWJUH. We anticipate 96 subjects will complete the study. Your time on this study will be through your post-op clinic visit (approximately 4 weeks after surgery). We anticipate this study will take 2 years to complete.

What will I be asked to do if I take part in this study?
If you take part in the research, you will be randomized (like flipping a coin) to receive either Exparel or Marcaine for pain control during your cardiac surgery. You will complete a quality-of-life survey (takes < 5 minutes) prior to surgery and at your post-op clinic visit. Study staff will collect information from your medical records.

What are the risks of harm or discomforts I might experience if I take part in this study?
Both medications in this study are FDA approved for this indication. The risks of each drug are very similar. Subjects undergoing cardiac surgery at RWJUH would normally

receive Exparel. Therefore, the only risk specific to this study is if one medication is less effective at controlling pain then the other. If any side effects occur, they will be managed per standard of care.

Common side effects of Marcaine include:

- nausea,
- vomiting,
- chills or shivering,
- headache,
- back pain,
- dizziness,
- problems with sexual function,
- restlessness,
- anxiety,
- dizziness,
- ringing in the ears,
- blurred vision, or
- tremors.

Side effects of Exparel include:

- dizziness,
- drowsiness,
- nausea,
- constipation,
- vomiting,
- itching,
- headache,
- back pain, or
- swelling in hands or feet.

Loss of confidentiality - Every effort will be made to maintain patient confidentiality. Only study personnel will have access to the study data.

Are there any benefits to me if I choose to take part in this study?
There may be no direct benefit to you for participating in this study. However, future cardiac patients may benefit from the results of this study.

What are my alternatives if I do not want to take part in this study?
This study is being done for research purposes. Therefore, your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is

learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any costs to me to take Part in this study?
There are no costs for participating in this study.

Will I be paid to take part in this study?
You will not be paid for participation in this research study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

All information collected during the study will be stored on the Surgery Department's password protected server only accessible to study team. When the study is closed all identifiers and links will be destroyed.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration

A description of this clinical trial will be available on 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 will happen to my information collected for this research after the study is over?
After information that could identify you has been removed, de-identified information collected for this research may be used for other research conducted by this PI without obtaining additional informed consent from you.

What will happen if I am injured during this study?

Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, as described in the Risks section. It is possible that during the course of this study, new adverse effects of Exparel® or Marcaine® may be discovered and result in personal injury. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded

programs, e.g., Medicare, Medicaid or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

Who Can I Contact If I Have Questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Leonard Lee, MD, Rutgers' RWJMS, Department: Surgery, 1 RWJ Place, East Tower, Suite 838, New Brunswick, NJ 08903, 732-235-7766.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for

this study is to help investigators answer the questions that are being asked in the research.

What information about me will be used?

- Medical history,
- Results (cardiac test, radiology and laboratory)
- Treatments (medical and surgical)
- Hospital course

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study.
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Pacira Pharmaceuticals, Inc. may access de-identified study data.

Will I Be Able To Review My Research Record While The Research Is Ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Leonard Lee, MD, Rutgers' RWJMS, Department: Surgery,1 RWJ Place, East Tower, Suite 838, New Brunswick, NJ 08903

How Long Will My Permission Last?

There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

_____	_____	_____
Print Name of Subject	Signature of Subject	Date

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

_____	_____	_____
Person Obtaining Consent	Signature	Date

**For office use only
Copy of consent was given to the subject. _____