JOHNS HOPKINS MEDICINE

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Date: September 29, 2015
Principal Investigator: Gedge Rosson M.D
Application No.: NA_000759500075957

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Pre-operative Paravertebral Blocks to Decrease Post-operative Pain Following Mastectomy with Immediate Tissue Expander Reconstruction**

Application No.: **NA_00075957**

Principal Investigator: **Dr. Gedge Rosson**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov,at www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to see how well a pain medicine (ropivacaine) treats pain after breast reconstruction when it is injected near your spine to numb the nerves going to your chest. Previous studies have shown varying results in reducing pain, nausea, and sleeping problems after surgery.

The Food and Drug Administration (FDA) has approved the use of ropivacaine for local or regional pain relief for surgery. Also, ropivacaine is used in diagnostic and therapeutic procedures. In pregnant women ropivacaine is used for procedures performed during delivery.

People with planned breast removal followed by immediate breast reconstruction with tissue expanders may join this study.

How many people will be in this study?

About 70 women will join this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

A member of the study staff will ask you to complete some questionnaires. These questionnaires are used to determine your overall quality of life before your surgery. The staff member will also work with you to find out your overall pain level before your surgery.

Before your first breast surgery you will be randomly (by chance, like a flip of a coin) assigned to one of two groups: the study drug administration group or the placebo group.

- If you are randomized to the study drug administration group, you will receive ropivacaine injections. The standard vital sign monitors will be placed. You will be asked to sit. After administering light intravenous sedation, the skin of your back will be cleaned with antiseptic solution. The anesthesiologist will locate where you will receive the injections (the spaces between your vertebrae) by touching your thoracic spine (mid-back). Once located, a local anesthesia will be applied to each side of your mid-back after which you will receive the study injections. About 6-7 injections will be placed on each side of your mid back and each injection will be about 5ml (about 1 teaspoon). The procedure will take about 10-15 minutes. After you are given the injections, you will be asked to lie down. Please refer to the attached information sheet on paravertebral blocks for more information.

- If you are randomized to the placebo group, you will receive injections of an inactive substance (like salt water) that looks like the study drug but contains no active study drug. The standard vital sign monitors will be placed. You will be asked to sit. After administering light intravenous sedation, the skin of your back will be cleaned with antiseptic solution. The anesthesiologist will locate where you will receive the injections (the spaces between your vertebrae) by touching your thoracic spine (mid-back). Once located, a local anesthesia will be applied to each side of your mid-back after which you will receive the study injections. About 6-7 injections will be placed on each side of your mid

back and each injection will be about 5ml (about 1 teaspoon). The procedure will take about 10-15 minutes. After you are given the injections, you will be asked to lie down.

You will have an equal chance of being in either group. Neither you nor your doctor can choose the study group. Additionally, this study is "blinded" which means that neither you nor your doctors but only the study staff will know to which study group you have been assigned. However, in an emergency this information can be found and given to your doctors.

You will receive general anesthesia as you normally would and your breast removal surgery and breast reconstruction procedure will be done, per standard surgical techniques.

Following the surgery, standard pain control medicine will be available to you, per standard of care. Because you are in this study, you will be asked to complete a few short questionnaires. These questionnaires will tell us about any pain you might have. If you are able to go home the first or second day after your surgery, a study team member will call you to ask you some questions by phone. These questions will be about your pain, pain medicine use, and any problems you might be having. The expected length of hospital stay after your surgery is about one day.

When you return for your normal follow-up visit one week (7 days) after the surgery, a study team member will also meet with you to ask you about any problems you may be having and about any pain medicine you have been using. Additionally, you will be asked to complete three short questionnaires.

When you return for your normal follow-up visit 3 months (90-days) after your surgery, you will be asked to complete four short questionnaires. These questionnaires will tell the study team how you are doing and about any problems you might be having.

Two and 4 years after your surgery we will try to contact you over the phone and ask you to complete the same questionnaires.

How long will you be in the study?
You will be in this study for up to 4 years.

4. What are the risks or discomforts of the study?

Risks of Ropivacaine:
The study drug, ropivacaine, may cause certain side effects with the following levels of likelihood:

- Likely:
  - None

- Less likely (occurs in more than 10 of every 100 patients):
  - Low blood pressure
  - Irregular heartbeat
  - Nausea and vomiting
  - Back pain

- Unlikely (occurs in 1-10 of every 100 patients):
  - High blood pressure
  - Chest pain
  - Fever
  - Headache
  - Dizziness
  - Chills
  - Anxiety
  - Lightheadedness
  - Itching
  - Difficulty urinating
  - Tingling around your mouth
  - Numbness of your tongue

- Rare (occurs in less than 1 of every 100 patients, usually in the context of overdose or inadvertent intravascular injections):
  - Allergic reactions
  - Heart attack
  - Rash
  - Muscle stiffness and/or twitching
  - Seizure (uncontrollable shaking of your body)
  - Hearing problems
  - Vision problems
  - Speech problems

Risks of Study Procedures (will apply to both arms):
Possible problems caused directly by being stuck with a needle (whether you get the study drug or placebo) include: severe bleeding (less than 3 people out of 100), collapsed lung (less than 1 out of 200), headache after spinal injection (rarely), or infection in the fluid that surrounds your brain and spine (rarely). Rarely, brain abscesses can occur.

Risks of your breast removal surgery and reconstruction procedure will be explained in your surgical consent form. There are no increased risks related to the surgery and reconstruction procedure.

You may feel more anxious than usual simply because you know you are in a research study.

There is the risk that information about you may become known to people outside of this study. Although all efforts will be made to keep the study information confidential, there is always the possible loss of confidentiality.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Unknown Risks:
There may be side effects and discomforts that are not yet known.

5. Are there benefits to being in the study?

You may or may not benefit from being in this study. You may experience less pain after your surgery but this cannot be guaranteed. If you are randomized to receive placebo, no benefit is expected. If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

You do not have to join this study to receive the paravertebral block with your breast removal surgery and breast reconstruction procedure.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No. You or your insurance company will not be billed for the paravertebral block procedure.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

You will be asked to give us a list of other health care providers that you use.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Gedge Rosson at 410-955-9477. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Gedge Rosson at 410-955-9477 during regular office hours.

If you have an urgent medical problem related to your taking part in this study call 410-550-0500, and ask to speak with the plastic surgery resident on call.

15. What does your signature on this consent form mean?

- Your signature on this form means that: You understand the information given to you in this form, you
- You accept the provisions in the form and you

You agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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