KEY INFORMATION FOR *Comparison of 1%- Chloroprocaine vs. Hyperbaric Bupivacaine Spinals in Patients Undergoing Anorectal Surgery in an Ambulatory Surgery Center: A Double-Blind Randomized Controlled Pilot Trial*

We are asking you to choose whether or not to volunteer for a research study about how well 1%-chloroprocaine works versus bupivacaine. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if 1%-chloroprocaine-HCl spinal anesthesia will reduce the recovery times and discharge time of patients undergoing anorectal surgeries as compared to 0.75% bupivacaine spinal. Your participation in this research will last until you are ready for discharge.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The possible benefits of taking part in this study include fast onset, satisfying block, quick recovery, and minimal side effects. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Spinal anesthesia carries the risk of bleeding, infection, delayed ambulation, pain after block regression (back pain or transient neurological symptoms) and risk of urinary retention. Furthermore, local anesthetics, which are routinely used for spinal anesthesia, carry the risk of local anesthetic toxicity, neurotoxicity, and allergic reactions. *For a complete description of risks, refer to the Consent Document below.* You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr.Iyabo Muse. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 718-920-4187.
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Comparison of 1%-Chloroprocaine vs. Hyperbaric Bupivacaine Spinals in Patients Undergoing Anorectal Surgery in an Ambulatory Surgery Center: A Double-Blind Randomized Controlled Pilot Trial.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." **Her** name is Dr. Iyabo Muse. You can reach Dr. **Muse** at:
Office Address: 111 E 210th street
City, State Zip: Bronx, NY 10467
Telephone #: 718-920-4187
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by **Montefiore Medical Center Department of Anesthesia**

Why is this study being done?

Spinal block is a technique used to provide anesthesia during anorectal surgery. To perform the spinal, we use a needle to inject medication in the back that numbs the nerves. At our institution, it is the standard of care to perform anorectal surgery under spinal anesthesia using a drug called bupivacaine at a concentration of 0.75%. The goal of this study is to measure the difference, if any, between bupivacaine and another drug called 1%-chloroprocaine. We think 1%-chloroprocaine can decrease recovery time (time it takes the medication to wear off) and discharge time (time it takes before you are able to urinate and then go home). But more research needs to be done to prove this.

Both drugs, 1%-chloroprocaine and bupivicaine, are approved by the U.S. Food and Drug Administration (FDA) to be used in spinal anesthesia.

Why am I being asked to participate?

You are being asked to participate in this study because you are an adult that will undergo anorectal surgery. You were identified on the surgery schedule.

How many people will take part in the research study?

You will be one of **110** people who will be participating in this study.

How long will I take part in this research?

However long it takes for you to be ready for discharge is how long it'll take for you to complete this research study. You will not have to make any follow-up research related visits at Montefiore Medical Center after you have been discharged.

What will happen if I participate in the study?

If you are eligible for the study, we will assign you by chance (like a coin toss) to the 1%-Chloroprocaine group or the bupivicaine group. You will have a 50/50 chance of being assigned to the either group.

If you choose to participate, you will be randomized to one of the two spinal drug groups on the day of surgery. Everything else that follows is the standard of care and not affected by participating in the research. All patients will receive mild sedation for spinal anesthesia. All patients will get spinal anesthesia. You will be monitored during surgery (blood pressure, heart rate, and oxygenation). After surgery, you will go to the recovery area and a nurse will care for you. As a standard part of this care, the nurse will check the strength and sensation in your legs as well as when you can first urinate. After you are able to urinate, you may be discharged home.

You will be called within 24 hours by a nurse to follow-up on how you are doing and asked standard questions as well as two more questions related to the research: 1. Presence of nerve pain in the buttocks and thighs and 2. Inability to urinate, pass gas or defecate. If any of these are present, this will be communicated to an anesthesiologist who will advise you further. Temporary inability to urinate, pass gas or defecate and nerve pain can be a side effect of spinal anesthesia.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. The Web site will include a summary of the results but your specific information will not be shown. You can search this Web site at any time.

Information Banking (Future Use and Storage)

Data Stored with Identification Linking Code

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more assessible databases. These databases may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not

affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW
_____ I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to **Dr. Iyabo Muse at 718-920-4187**.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including “over-the-counter” remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- Please report all symptoms and reactions to drugs as well as any other complaints to the research study doctor.
- You may carry out all your normal daily activities.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

Risks of Chloroprocaine or Bupivacaine

Spinal anesthesia, which is the standard of care you would receive even if you do not participate in the research, carries the risk of bleeding, infection, delayed walking, pain after the block wears off (back pain) and inability to urinate. The drugs used in the spinal can rarely cause an allergic reaction, seizures, and changes in your heart rhythm and blood pressure.

Allergic Reaction to Study Drug

Any drug can cause an allergic reaction which could be mild or more serious. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. But participation in this research study will not increase your risk of an allergic reaction.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include fast onset, satisfying block, quick recovery, and minimal side effects.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time