BAYLOR RESEARCH INSTITUTE
Baylor Jack and Jane Hamilton Heart and Vascular Hospital
Dallas, TX

PARTICIPATION EXPLANATION AND CONSENT FORM

PROJECT TITLE: **The association between type of local anesthesia treatment and postoperative pain in patients having undergone arrhythmia surgery**.

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INTRODUCTION:

Before you say that you will be in this clinical trial (a kind of research study) you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the clinical trial is about and how it will be done. It will tell you about some problems that might happen during the clinical trial. It will also tell you about the good things that might happen for you during the clinical trial. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this clinical trial are giving you very important information about the clinical trial. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have been diagnosed as having an arrhythmia that requires a pacemaker or defibrillator.

Why Is This Study Being Done?

The purpose of this study is to compare the effects of two routinely used anesthetics, **Lidocaine** with **a mixture of Lidocaine and Bupivacaine** on you and other people with arrhythmias that require a pacemaker or defibrillator.

This research is being performed because we do not know if one of these two commonly used anesthetic regimens is better in terms of minimizing post-operative pain and/or patient movement during insertion of the defibrillator or pacemaker.

What is the Status of the Drugs involved in this study?

- **Bupivacaine** is currently approved by the US Food and Drug Administration.

- **Lidocaine** is currently approved by the US Food and Drug Administration.

How Many People Will Take Part In The Study?

About **300** people will take part in this study at this location.

What Is Involved In The Study?

You are scheduled to have either a pacemaker or defibrillator surgery. Before this surgery, you will be randomly assigned (by chance like flipping a coin) to receive either Lidocaine or a mixture of Lidocaine and Bupivacaine as a way to make the site of the incision numb. Receiving one of these medicines is approved and considered standard. Your surgery will then be done exactly in the same manner as it would be done even if you were not in the study.

Data will be collected about how each of these works. This information will be collected and compared to see if one of these treatments is better and has less problems.

There are only two things that are different in this study from if you had surgery in the standard way. The first is that the type of medicine used will be randomly assigned, rather than you or your surgeon choosing which of these will be used. The second difference is that data will be collected and analyzed about your surgery and hospital experience.

How Long Will I Be In The Study?

You will be in the study for the day of your pacemaker or defibrillator surgery. All the information we need from you will be taken on the day of your defibrillator or pacemaker surgery.

The researcher may decide to take you off the study if he/she decides that it is important for them to be able to choose which drug you have before the surgery.

You can stop taking part in this study at any time. However, if you decide to stop taking part in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of The Study?

There is no evidence that one medication (Lidocaine or Bupivacaine) is better than the other, and if you were not in this study your doctor would decide which medication would be used for your surgery based on his or her preference. One of these medications would have been given to you for your surgery even if you did not participate in this study. However, if you participate in this study, we will randomly assign you to receive either Lidocaine or a mixture of Lidocaine and Bupivacaine.

While on the study, you are at risk for some side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs may be given to make side effects less serious and uncomfortable. Many

side effects go away shortly after Lidocaine or Bupivacaine are stopped, but in some cases side effects can be serious or long lasting and permanent.

Risks of Lidocaine: allergic reaction, low blood pressure, difficulty breathing, fast heart rate, slow heart rate, feeling light headed, tremors, seizure, chest pain, weak pulse, nausea, vomiting, anxiety, speech problems and headache.

Risks of Bupivacaine: allergic reaction, low blood pressure, difficulty breathing, fast heart rate, slow heart rate, feeling light headed, tremors, shivering, weak pulse, nausea, vomiting, anxiety, speech problems and headache.

While these drugs do have potential risks, remember that you would get one of these drugs even if you were not in the study, so your risks are no greater for being in the study than if you were not in the study.

Your doctor may be an investigator in this research study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor.

Are There Benefits to Taking Part in The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What Other Options Are There?

Instead of being in this study, you have the following options:

You may still have your surgery, and your physician will choose what medication to use for your procedure. If you choose not to participate your information will not be used for this study. If you do not participate in this study it will not affect you treatment or surgery in any way.

Please talk to your regular doctor about these and other options.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on the study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Research Institute get your permission before giving any of your health information to other people. There are people who need to review your information to make sure the study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to Baylor Research Institute to give other people information about your health as needed for the research project. These groups include people who work for Baylor Research Institute (including the Institutional Review Board), the US Food and Drug Administration, and the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs**.** Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. This could also be information about drug or alcohol abuse.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for us to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in the research study.

If you give permission to Baylor Research Institute to give other people information about your health and the other people are not part of the group that must obey this law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify Baylor Research Institute in writing at 3310 Live Oak, Suite 501, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will not expire at the end of the study.

A description of this clinical trial is available on 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. The www.ClinicalTrials.gov study ID is NCT01300377.

What Are the Costs and Will I Be Paid?

There are no additional costs to you for being in the study. You (or your insurance company) will be responsible for paying all costs of your surgery and hospital stay, including the costs for administering the drugs described in the study.

You will not be paid for being in the study.

What are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about the study or have a research-related injury, contact **Dr. Cara East** at **214.820.2273**. If it is not during business hours please page Ja Karsha Culton at 214-521-1009.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part.

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

Statement of Principal Investigator (if PI did not sign above):

As Principal Investigator of this study, I confirm that to the best of my knowledge this subject has voluntarily agreed to take part in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above.

_____	_____	_____
Signature of Principal Investigator	Date	Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to take part as a subject in this research project.

_____	_____	_____
Signature of Subject	Date	Time