St. Elizabeth's Medical Center
A STEWARD FAMILY HOSPITAL

Research Informed Consent Form

St. Elizabeth's IRB Approval:
IRB#: 00808
Approval Date: 04-SEPT-2020
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Approval Expires: 03-SEPT-2021

Subject's Name:	
Date of Birth:	**MRN:**

Protocol Title:	Pilot Randomized Control Trial: Comparing the Effectiveness of Buzzy versus Intradermal Lidocaine for Peripheral Intravenous Cannulation in Adults
Sponsor:	N/A
Principal Investigator (PI):	Dr. Michael Schoor Department of Anesthesiology 736 Cambridge Street Brighton, MA 02135 Michael.Schoor@steward.org 617-789-3000
Study Coordinator:	Dr. Danielle Levin Department of Anesthesiology 736 Cambridge Street Brighton, MA 02135 Danielle.Levin@steward.org 617-789-3000

About this Consent Form

You are being asked for your consent to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. Please read this consent form carefully and take your time making a decision. The form may contain words that you do not understand. Please ask questions about anything you do not understand. If you agree to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

What should you know about being in a research study?

- Participation in research is voluntary.
- It is your choice to participate or not.
- You can agree to participate and later change your mind.

- If you decide not to participate or to stop being in the research study, your decision will not be held against you and will not impact the care you receive at St. Elizabeth's Medical Center.
- We encourage you to discuss whether to participate with others (for example, your friends, family, or other doctors).
- You can ask any questions before making a decision.
- Before making your decision, you should have a good understanding of the study.

Research Summary (Key Information)
The information in this section gives you an overview of the key information you should know about the research study and is intended to be an introduction to the study only. Complete details of the study are included in the sections that follow. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

IV placement is necessary for surgical procedures. Unfortunately, some patients say that placing an IV is painful. We are conducting this study to evaluate two pain relieving techniques that could make the placement of the IV more comfortable.

- The purpose of this study is to compare the effectiveness of the Buzzy® device with that of the injection of numbing medication underneath the skin for pain relief of IV placement in adults. This device has been FDA approved for use.
- Study participation will take about 20 minutes.
- Either the Buzzy vibrating ice pack will be placed on your arm for 3 minutes, or you will receive an injection of numbing medication prior to your IV placement. You will be randomly assigned to one of the two study groups by chance.
- After the IV placement you'll be asked to complete a survey about pain.
- You do not have to participate in the study to receive your regular care and can choose to get an injection of numbing medication outside of the study.
- Potential benefits include that you may experience less pain during the IV placement.
- Possible risks include discomfort or loss of confidentiality.

Why are you being invited to participate in this research study?
You are being asked to volunteer in this a research study because you will be receiving an IV today and are a patient at St. Elizabeth's Medical Center.

We are inviting patients that are scheduled to go to the operating room and need an IV placed to be part of this study.

Participation is voluntary.
It is your choice whether or not to participate. If you chose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

Purpose: Why is this research study being conducted?
IV placement is necessary for surgical procedures. Unfortunately, some patients say that placing an IV is painful. This research is being done to find ways to make IV placement more comfortable. We are conducting this study to evaluate two pain relieving techniques that could make the placement of the IV more comfortable, using a Buzzy device and injecting numbing medication.

Currently, some medical providers administer the IV without any pain-relieving techniques. Some medical providers inject a numbing medication underneath the skin prior to the IV placement. This requires an additional needle stick. Some medical providers place a device called Buzzy® on a patient's arm prior to the IV placement. The Buzzy® device is the combination of an ice pack and a vibrator in the shape of a bumble bee. Literature shows that the Buzzy® device makes IV placement more comfortable for children, but there is minimal data in regard to whether it is helpful for adult patients.

We are conducting this study to compare the effectiveness of the Buzzy® device with that of the injection of numbing medication underneath the skin for IV placement in adults. The Buzzy® device is approved by the Food and Drug Administration (FDA) for the control pain from injections, IVs, phlebotomy, and cosmetic injections, as well as relief of musculoskeletal pain.

Who is conducting this research study, and where is it being conducted?
Dr. Michael Schoor is conducting this study at St. Elizabeth's Medical Center. The study is not funded by an outside sponsor.

Your health care provider is a research investigator for this research study and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate, your care at St. Elizabeth's Medical Center and/or with your health care provider will not be affected in any way.

How many people will participate in this research study?
About 40 people will take part in this research study at St. Elizabeth's Medical Center.

Duration: How long will you be in this research study?

You will be in this study for the duration of the IV placement. You will be asked to fill out a very brief questionnaire after the IV placement. Your participation will be less than 30 minutes.

Procedures: What do you have to do if you are in this research study?
If you choose to participate in this research study, the pain-relieving technique that you get will be chosen by chance. Neither you nor the study doctor will choose what technique you get. Once you sign the consent form, the study doctor will look at a predetermined computer-generated random number sequence that will determine which technique you will receive. You will have an equal chance of being given each technique.

Your study doctor will administer that technique, followed by an IV placement.

- The Buzzy vibrating ice pack will be placed on your arm with an elastic band around it, and it will remain there as your arm is cleaned and as the doctor is getting ready to insert the IV. The Buzzy device will be removed once the IV is inserted. The Buzzy device will be available for you to look at as we are discussing this study.
- If you are in the other group, an elastic band will be placed around your arm without the Buzzy device, and the elastic band will be removed once the IV is inserted. After the elastic band is placed on your arm, your arm will be cleaned, and then lidocaine will be injected very close to were the IV will be placed. The IV will be placed within about a minute from the time when the lidocaine was injected.

No additional data will be collected from your medical record. After the insertion of the IV, you will answer a brief questionnaire about your experience with the IV placement. This completes your participation in this research study.

Risks, discomforts or inconveniences: What are the risks of this research study? What could go wrong?
It is very unlikely that you will have any risk from taking part in this study.

There is a slight chance that you might not like the Buzzy vibrating ice pack being applied to your arm, but a lot of children have reported that they like when this vibrating ice pack is applied to their arm.

The risks associated with the lidocaine injection are minor discomfort, bruising, fainting, and infection.

There is the risk of loss of confidentiality. Although security measures are in place to protect your private information, information about you may become known to people outside this study.

Benefits: Are there any benefits from being in this research study?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include less pain with the IV administration. Also, the health care provider that will be administering the IVs in the future might end up having less risk of an accidental needle stick injury as a result of this study.

Alternatives: What are your options if you do not want to be in the study?
You do not have to join this study. Your doctor can discuss other healthcare choices with you.
Your other options may include: (1) getting the IV with no pain relief, (2) getting the IV after the injection of the numbing medication in your arm, or (3) using the Buzzy device with the IV insertion.

Future Use of Information & Biospecimens: Will your information or samples be used for research in the future?
Private information collected from you during this study will NOT be used for future research studies or shared with other researchers for future research, even if the information identifying you are removed from the private information.

Costs: Are there costs to you for participating in the research?
There will be no additional costs to you for participating in the research.

Although research funds will pay for some research-related items and services, we may bill your health insurer for routine items and services you would have received even if you did not take part in this research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If your insurance does not pay, or pays only a portion of the costs, we may bill you for any unpaid amounts. If you have any questions about costs to you that may result from taking part in the research, please speak with the research staff.

Compensation: Will you be paid or receive other compensation to participate in this research study?
You will not be paid to participate in this study.

In Case of Injury while Participating in the Research
We will offer you the care needed to treat any injury that directly results from taking part in this research, including first aid, emergency treatment and follow-up care. We reserve the right to bill your insurance company or other third parties, if appropriate, for the cost of such care. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer. Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research, tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed in this consent form.

Confidentiality: Will your information be kept private?

Your identity and records throughout the research study will be kept confidential, in accordance with applicable law. The results of the study will only be published or presented as group data. No individual participants will be identified. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Study Sponsor, the Food and Drug Administration (FDA), and the Institutional Review Board, or others in order to meet regulatory requirements.

Are there other things you should know about?

If we find out about new information from this research or other research that may affect your health, safety or willingness to stay in this research we will let you know as soon as possible.

ClinicalTrials.Gov

A description of this clinical trial will be available on *http://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.

Contact Information

If you have questions, concerns, complaints, or think you have been injured due to the research, contact a member of the research team at:
Dr. Michael Schoor at Michael.Schoor@steward.org or at 617-789-2777.

This research has been reviewed by the St. Elizabeth's Medical Center Institutional Review Board (IRB). You can contact the IRB for any of the following reasons:

- If you have any research-related comments, concerns or complaints
- If you have questions about your rights as a research participant
- If the investigator/research contact cannot be reached
- If you want to speak with someone other than the investigator or research staff

Call the IRB Office at (617) 789-2804, or contact by mail at the following address:

Institutional Review Board (IRB) Office
736 Cambridge Street
Boston, MA 02135

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (PHI)

Your health information is protected by a federal law called the Health Information Portability and Accountability act (HIPAA). As part of this study, we will be collecting and sharing information about you with others. This section contains information about the federal privacy rules and the use of your information.

Protected Health Information (PHI)
By signing this Informed Consent Document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists in your medical record (such as demographic information, laboratory results, discharge summaries), as well as any new information generated as part of this study through the tests and procedures described in this Informed Consent Document. This information is known as your Protected Health Information, or PHI.

Why We Are Using and Sharing Your PHI
The reason for using and sharing your Protected Health Information, PHI, is to conduct and oversee the research as described in this Informed Consent Document.

People/Groups at St. Elizabeth's Medical Center Who Will Use Your PHI
Your PHI may be shared with the investigators listed on this consent form as well as the supporting research team (i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants). Your PHI may also be shared with the Institutional Review Board of **St. Elizabeth's Medical Center** as it is responsible for reviewing studies for the protection of the research subjects.

People/Groups Outside of St. Elizabeth's Medical Center with Whom Your PHI Will Be Shared
We will take care to maintain confidentiality and privacy about you and your Protected Health Information, PHI. We may share your PHI with the following groups so that they may carry out their duties related to this study:

- Your health insurance company, for portions of the research and related care that are considered billable.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities include any other agency that may have regulatory oversight for your study

Those who receive your PHI may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

No Expiration Date - Right to Withdraw Authorization
Your authorization for the use and disclosure of your Protected Health Information, PHI, in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your PHI at any time by

notifying the Principal Investigator in writing. If you would like to withdraw your authorization, please send a letter notifying the Principal Investigator to Dr. Michael Schoor 736 Cambridge Street, Boston, MA 02135. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your PHI that has already been used or disclosed before the Principal Investigator receives your letter.

Right to Access and Copy Your PHI

If you wish to review or copy your Protected Health Information, PHI, as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator. You may not be allowed to inspect or copy your PHI until this study is completed or terminated.

Documentation of Informed Consent and Authorization

Research Participant's Statement & Signature

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

_____	_____	_____	_____
Date	Time	Printed Name of Participant	Signature of Participant

Statement & Signature of Principal Investigator or Person Obtaining Consent

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).

_____	_____	_____	_____
Date	Time	Printed Name of Research Investigator or Associate	Signature of Research Investigator or Associate

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box):

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present. Please specify: _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

_____	_____	_____	_____
Date	Time	Printed Name of Witness	Signature of Witness

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

_____	_____	_____	_____
Date	Time	Printed Name of Witness	Signature of Witness