Official Title:	**A Randomized Clinical Trial of Buzzy versus Vapocoolant in Pain Relief during a venipuncture procedure in a pediatric Emergency Room**
NCT number:	unavailable
Document Type:	Legal guardian consent
Date of the Document:	December 17, 2019

Parental Permission form

Title of research study: **A randomized clinical trial of buzzy versus vapocoolant in pain relief during a venipuncture procedure in a pediatric Emergency Room**

Version Date: ***December 17, 2019***

Investigator: ***Dr. Jill C Fennell***

Key Information: The following is a short summary of this study to help you decide whether or not to let your child to be a part of this study. More detailed information is listed later on in this form.

Why is my child being invited to take part in a research study?

Your child is being invited to take part in a research study because he/she is in need of blood work, and/or an intravenous (IV) line placement for medications.

What should I know about a research study?

Someone will explain this research study to you.
Whether or not you let your child take part is up to you.
You can choose not to let your child take part.
You can agree to let your child take part and later change your mind.
Your decision will not be held against you or your child.
You can ask all the questions you want before you decide.

Why is this research being done?

Placement of intravenous (IV) line and taking blood sample are common practices in the pediatric Emergency department for work up and treatment. Unmanaged needle stick pain in pediatric patients have been associated with needle phobia, greater pain with future sticks, anxiety associated with other medical procedures, healthcare avoidance and increased adult pain sensitivity.

Different methods have been used for management of acute pain associated with needle sticks. Among them, vapocoolants, and buzzy are frequently used methods to help pediatric patients for pain relief related with the needle sticks. Vapocoolants are volatile refrigerated liquids used prior to the needle sticks. The buzzy is a vibrating palm-sized device with removable ice wings used during the needle sticks.

Some research results show that vapocoolants are ineffective in children when compared to placebo or no treatment. The investigators believe that the sensation of cold on a child's skin may be perceived as painful by the child.

The main purpose of this study is to compare the effectiveness of pain relief using different methods, the buzzy, vapocoolant and placebo while the patient is having an IV line placement or a blood draw.

How long will the research last and what will my child need to do?

We expect that your child will be in this research study for about 10 minutes.

Your child will be randomly assigned into one of the three study groups, i.e. the buzzy bee vapocoolant or placebo, and receive the assigned intervention before or during the needle insertion procedure. Meanwhile, our research team will take a videotape of your child while the nurse is doing the needle insertion. .

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want my child to be in this research?"***

Is there any way being in this study could be bad for my child?

This study involves no more than minimum risk to the participants. Participant may have a local reaction to the device used. If that happens to your child, your child may not be included in the research study.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for my child? (Detailed Risks)"***

Will being in this study help my child in any way?

There are no benefits to your child from his/her taking part in this research. We also cannot promise any benefits to others from your child's taking part in this research.

What happens if I do not want my child to be in this research?

Participation in research is completely voluntary. You may choose not to let your child enroll in this study.

Your child's alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt your child, talk to the research team at *716-323-0055.* You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your child's rights as a participant in this research

Your questions, concerns, or complaints are not being answered by the research team.
You cannot reach the research team.
You want to talk to someone besides the research team.
You want to get information or provide input about this research.

How many people will be studied?

We expect about 168 people here will be in this research study.

What happens if I say yes, I want my child to be in this research?

If you decide to let your child take part in this study, your child will receive one of the three pain relief methods for the placement of IV line or blood draw. Your child will be randomly assigned into one of the three groups: buzzy bee, vapocoolant, or placebo.

The method your child gets will be chosen by chance, like flipping a coin. Neither you nor we will choose what method your child gets. Your child will have an equal chance of receiving each of the three methods.

While the nurse is taking blood or placing IV line, we will videotape your child. The investigators will review the tape later on and give pain scores related with the procedure.

We will also ask you and your child to complete a pain evaluation form before and after the needle sticks procedure.

Other than these study procedures, your child will receive routine medical care. Your child participation in this study will end once you and your child complete the post needle stick pain evaluation form.

What are my responsibilities if my child take part in this research?

If your child takes part in this research, you and your child will be responsible for filling out two forms for assessing your child's pain related with the needle stick.

What happens if I say yes, but I change my mind later?

Your child can leave the research at any time and it will not be held against you or your child.

If you decide to let your child leave the study, let the research team know, so we will stop the study procedure immediately.

If your child stops being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue collecting data from your child's routine medical care. If you agree, this data will be handled the same as other research data.

Is there any way being in this study could be bad for my child? (Detailed Risks)

This study involves no more than minimum risk to the participants. Participant may have a local reaction to the device used. If that happens to your child, your child may not be included in the research study.

In addition, breaching confidentially is a potential risk for this study. We will take all precautions to prevent this from happening.

We will videotape your child for this study, which is also a confidentiality risk. The study coordinator will transfer the video from the camera to a password protected secure online drive. Then she will erase the video from the camera. The video images saved on the secure online drive will be erased at the end of the study.

The device and the vapocoolant used in this study have been approved by Food and Drug Administration (FDA) for releasing pain associated with needle sticks.

What happens to the information collected for the research?

All research data collected for this study will be locked up in secure file cabinet in the research office. The video will be erased from the camera after being saved in a password protected online secure drive. Only the study coordinator and the investigators can gain access to the data and video. Video will be erased from the online secure drive at the end of the study.

Your child's information that are collected as part of this research will not be used or distributed for future research studies, even if all of your child's identifiers are removed.

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization.

If the research team uncovers possible concerns for abuse, neglect or reportable diseases this information may be disclosed to the appropriate authorities.

The IRB and the FDA will be granted direct access to your child's medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your child's name and other identifying information confidential.

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include needing more than one try for inserting the IV line or taking blood draw. Your child may also be removed if there is a problem with the video tape or the FACES scale.

What else do I need to know?

The results of this research may be presented at conference and published in a scientific journal, but the results will be presented as group data, and no participant's identity will be published.

You or your child will not be paid for participating in this study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about your child's health information that will be obtained by the researchers when your child participates in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about your child as part of this research study?

__X___ Information from your child's full medical records: Demographic data, ED visit date and time.

___x__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

___x__ KALEIDA Health, Buffalo NY

C. Who is authorized to receive the information from the information providers identified in (B)?

__x__ Principal Investigator or designee

D. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__x___ Other medical investigators participating in this research study including the doctors who will be watching the videos

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your child's information for this research project?

__ x ___ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about your child.

___ x __ d. Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about your child unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Dr. Jill C Fennell
Division of Emergency Medicine
UMMD Pediatrics
5th Floor, Conventus Building
1001 Main Street,
Buffalo NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your child's individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which your child is otherwise entitled. If you decide not to sign this authorization, your child will not be able to participate in the research study.

Should you agree to participate in this research, this consent document will be placed in your child's medical record.

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent

Date

Printed name of person obtaining consent