PARENTAL CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study

Invitation

You are invited to allow your child to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to allow your child to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why is your child being asked to be in this research study?

Your child is being asked to be in this study because he/she is between the ages of 5-11 years old and requires dental work requiring local anesthetic on both sides of the mouth.

What is the reason for doing this research study?

An important aspect of behavior guidance in pediatric dentistry is the control of pain during dental procedures. Dental procedures can be carried out more effectively if a child is not in pain. The use of local anesthetic is generally indicated when teeth require restorative treatment or extraction. Dental injection is generally associated with a negative response in children. If a child experiences pain during a dental procedure, their future as cooperative dental patients may be damaged. The reason for doing this study is to determine if the use of the DentalVibe reduces pain during local anesthetic injection. The DentalVibe is a handheld device that delivers vibration to the tissue around the injection site. The device is FDA approved for use in children.

What will be done during this research study?

One appointment your child will receive local anesthetic dental injection with the DentalVibe turned on and at one appointment your child will receive local anesthetic dental injection with the DentalVibe off. Your child will be randomly assigned (ie., similar to flipping a coin) as to which appointment the DentalVibe will be on and which appointment it will be turned off. Immediately after injection, your child will be shown the Wong Baker FACES pain rating scale and asked to rate the amount of discomfort experienced during the injection by pointing to the face or number. Face 0 being no hurt and 10 being the worst hurt. Dental treatment will then be completed.

What are the possible risks of being in this research study?
There are no known risks associated with participating in this study.

What are the possible benefits to your child?
There is a potential benefit that your child may have less pain during the injection of local anesthetic.

Your child may not get any benefit from being in this research study.

What are the possible benefits to other people?
Potential benefits include the possibility of identification of an effective device to reduce pain during local anesthetic injections in children. This could lead to better behavior and more positive experiences in the dental clinic.

What are the alternatives to being in this research study?
Instead of being in this research study you can choose not to allow your child to participate.

What will allowing your child to be in this research study cost you?
There is no cost to you for your child to be in this research study.

Will you or your child be paid for being in this research study?
Neither you nor your child will be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the Department of Growth and Development, Section of Pediatric Dentistry of the University of Nebraska Medical Center.

What should you do if your child is injured or has a medical problem during this research study?
Your child's welfare is the main concern of every member of the research team. If he/she is injured or has a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about your child be protected?
Your child has rights regarding the protection and privacy of his/her medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include his/her medical record number, address, birth date, medical history, the results of physical

exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your child's research and medical records will be maintained in a secure manner.

Who will have access to information about your child?
By signing this consent form, you are allowing the research team to have access to your child's PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your child's PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share his/her PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that the subject's information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - The Food and Drug Administration (FDA)

You are authorizing us to use and disclose your child's PHI for as long as the research study is being conducted.You may cancel your authorization for further collection of your child's PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, your child will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your child's identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:
UNMC Pediatric Dental Residency

Childrens Hospital and Medical Center
8200 Dodge St
Omaha, NE 68114

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you decide not to give permission for your child to be in this research study?
You can decide not to give permission for your child to be in this research study. Deciding not to be in this research will not affect your child's medical care or his/her relationship with the investigator or the Institution. Your child's doctor will still take care of him/her. Your child will not lose any benefits to which he/she is entitled.

What will happen if you decide to stop your child's participation once it starts?
You can stop your child's participation in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff.Deciding to withdraw will otherwise not affect your child's care or relationship with the investigator or this institution. Your child will not lose any benefits to which he/she is entitled.

Your child may also be taken off the study if:

- Your child's behavior does not allow treatment to safely be completed in the dental clinic. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your child's rights as a research subject?
Your child has rights as a research subject. These rights have been explained in this

consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning his/her rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to give permission for your child to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to permit your child to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Parent/Guardian _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the parent(s)/guardian(s) of the subject. In my judgment, the parent(s)/guardian(s) possesses the legal capacity to give informed consent for the subject to participate in this research and is voluntarily and knowingly giving informed consent.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel
Principal

* Johnson, Christopher
alt #: 402-559-6100
degree: DDS

Faculty Advisor
Allen, Keith
phone: 402-559-5756
alt #: 402-559-6408
degree: PhD