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University at Buffalo
The State University of New York
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Office of Research Compliance | Clinical Research Institute on Addictions
1021 Main Street | Buffalo, NY 14203
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"Parent Permission for a Child to Participate in a Research Study"

Title of research study: Sevoflurane concentrations in children

Version Date: August 20, 2024

Investigator: Jerrold Lerman

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

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

Your child is being invited to take part in a research study because we wish to record how rapidly the anesthetic concentrations increase in the anesthesia machine that we use to anesthetize your child while he/she goes to sleep for surgery at Oishei Children's Hospital.

"What should I know about a research study?

Someone will explain this research study to you. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

You can ask all the questions you want before you decide."Why is this research being done?

Your child will undergo anesthesia with an anesthetic machine that is FDA approved and used as part of regular standard of care to administer anesthesia for his/her surgery: either the Drager Apollo or the GE Ohmeda. These machines are deployed in the operating rooms on the second floor (Drager Apollo) or the third floor (GE Ohmeda). We want to learn if the anesthetic (sevoflurane) concentration increases more slowly in one anesthetic machine than the other. I will record the

anesthetic concentrations and vital signs while your child undergoes a routine induction of anesthesia during the first 10 minutes. Once I have collected the data from all 24 children who will participate, the data will be compiled and compared for the two anesthesia machines to determine whether the increase in the sevoflurane concentrations for the two machines differ and if so, by how much. This could have bearing on which machine should be preferred for induction of anesthesia in children.

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

This research study will take place during the first 10 minutes of anesthesia. The anesthetic will be the usual, standard anesthetic with all the usual monitors throughout. I am asking your permission to record the anesthetic concentrations and vital signs from the monitors during the first 10 minutes of the anesthesia. The same data are stored in your child's electronic anesthesia record as per standard of practice. After the study is complete, the anesthesia and surgery will proceed as is customary.

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?

No. There are no additional risks to your child's health from participating in this study as no identifiable information will be recorded.

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

There are no direct benefits to your child from taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, once all the data are collected, the findings may identify that one of the two anesthetic machines provides a more efficient/rapid induction of anesthesia compared with the other.

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

Participation in research is completely voluntary. Your alternative to participating in this research study is not to participate in which case your child's anesthetic will be unchanged and proceed as usual.

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

Anesthesia will proceed as has been described to you by your child's anesthesiologist. If you agree to enroll your child in this study, the only addition is that I shall record your child's anesthesia concentrations and vital signs during the first 10 minutes of anesthesia. The study ends at 10 minutes of anesthesia.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt your child, you may call me, Dr. Jerrold Lerman, the principal in this study at (716) 323-6570. 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 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?

I plan to enroll about 28 children in this research study.

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

Anesthesia will be induced as is our standard practice using the flavored mask your child chose, followed by nitrous oxide in oxygen and then 8% sevoflurane. The anesthetic induction is usually complete by 10 minutes. During those 10 minutes, I will simply record the anesthetic concentrations and vital signs as they appear on the computer screens. At 10 minutes I will stop recording the anesthesia data and the study ends.

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

None.

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

You can withdraw your child from the research study at any time. Withdrawal will not change or affect your child's anesthetic in any way and all your child's data will be deleted from our research records.

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

There are no known risks associated with participating in this research. Recording your child's anesthetic data has no associated risks. No identifiable data will be recorded. More information can be found in **"What happens to the information collected for the research?"**

What happens to the information collected for the research?

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 information include the IRB and representatives of Kaleida. The data collected from the anesthetic monitors will be stored on an encrypted laptop that belongs to Dr. J. Lerman. No other person has access to the password for this laptop other than me.

Your child's study information will not be used for future studies, even if information that identifies them is removed.

We may publish the results of this research. However, no identifiable information will be disclosed.

A description of this study 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.

Federal law provides additional protections of your 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 this study can remove your child from the study without your approval. Possible reasons to remove your child from the study include complications during the induction of anesthesia that are associated with standard of care and unrelated to participation in this study such as unexpected airway complications and allergy to inhalational anesthetics. If your child is removed from the study, I shall personally inform you of the reason and how to proceed if follow-up is required.

What else do I need to know?

Will I get paid for my child's participation in this research?

You will not be paid for participating in this study.

What will I be told about clinically relevant research results?

If you wish to receive the final publication from the study, you may contact the investigator (Dr. Jerrold Lerman) by calling Dianne at the Department of Anesthesia (716) 323-6570 and requesting a copy of the final publication.

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 that will be obtained by the researchers when you participate 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?

_____ None.

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

__X___ KALEIDA Health, Buffalo NY

__X___ Principal Investigator, Dr. Jerrold Lerman

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 information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities or as required by law, including but not limited to:

__X___ The organization(s) responsible for administering this research, Oishei Children's Hospital and The Research Foundation of the State University of New York, University at Buffalo.

Your 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 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.

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. Jerrold Lerman, Dept. of Anesthesia, 1001 Main ST., Suite K-3502, Buffalo 14203.

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with to collect your 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 your child's participation 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

[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. *Note: you must have prior IRB approval to utilize the short form of consent documentation.]

☐ My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process