### SK_THSC-research-ethic2

# Research Consent Form

# (Parent/Legal Guardian)

**Title of Research Project:**

Needs Analysis and Time Flow Study to Assess Endoscopic Ear surgery

**Principle Investigator:**

Dr Adrian Lewis James Principle Investigator 416 813 2191

**Co-Investigators:**

Arushri Swarup Co-investigator 416 813 6767

**Purpose of the Research:**

Surgeons use a variety of special tools for ear surgery, including endoscopes which are used to look inside the ear and other tools (known as “instruments”) to complete the operation. We would like to see if it is possible to make better surgical instruments to help surgeons complete surgery more effectively. To do this we would like to study how surgeons use instruments in the ear so we can understand which instruments could be improved.

**Description of the Research:**

In this study we would like to record how long it takes for your child’s surgeon to complete different parts of his or her surgery. We would also like to count how many times the surgeon uses different instruments during the operation. This will help us understand which parts of the surgery take the surgeon a long time to complete and how to improve instruments to increase efficiency of the surgery in future. We would like your permission to do this during your child’s ear operation.

No extra tests or treatments are needed if your child takes part in this study.

We expect this study will carry on for about two years and then the research records will be deleted. We would like to keep the ear models and use them for teaching anatomy and surgery. We will not be recording private information such as your child’s name or address.

**Potential Harms:**

There are no potential harms from taking part in this study.

**Potential Discomforts or Inconvenience:**

There are no potential discomforts or inconveniences from taking part in this study.

**Potential Benefits:**

**To individual subjects:**

There are not likely to be any benefits to your child from taking part in this study.

**To society:**

We expect that the information we learn from this study will improve the way we operate on future patients with better tools.

**Research Study Results:**

Upon study completion, the results of the study will be shared with you.

**Confidentiality:**

We will respect your privacy. No information about who your child is will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

Sick Kids Clinical Research Monitors may see your child’s health record to check on the study. By signing this consent form, you agree to let these people look at your child’s records. We will put a copy of this research consent form in your child’s patient health record and give you a copy as well.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. Following completion of the research study the data will be kept as long as required then destroyed as required by Sick Kids policy. Published study results will not reveal your child’s identity.

**Reimbursement:**

You will not incur any expenses by being involved with this study so there will be no reimbursement.

**Participation:**

When your child is older and able to decide for themselves, we will check with him or her that they are willing to continue participating with this study. If you choose to let your child take part in this study you can choose to take your child out of the study at any time and we will remove their data from the research files on request. The care your child gets at Sick Kids will not be affected in any way by whether your child takes part in this study.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study. During this study we may create new tests, new medicines, or

other things that may be worth some money. Although we may make money from these findings, we

cannot give you or your child any of this money now or in the future because your child took part in

this study.

If your child becomes ill or is harmed because of study participation, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

**Sponsorship**

Dr. Adrian James and the Department of Otolaryngology at The Hospital for Sick Children are the sponsors of this study

**Conflict of Interest:**

Dr. Adrian James and the other research team members have no conflict of interest to declare.

**Consent** :

By signing this form, I agree that:

1) You have explained this study to me. You have answered all my questions.

2) You have explained the possible harms and benefits (if any) of this study.

3) I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child taking part in the study will not affect my child’s health care at Sick Kids.

4) I am free now, and in the future, to ask questions about the study.

5) I have been told that my child’s medical records will be kept private except as described to me.

6) I understand that no information about my child will be given to anyone or be published without first asking my permission.

7) I have read pages 1-3 and I agree, or consent, that my child\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ may take part in this study.

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Printed Name of Parent/Legal Guardian Parent/Legal Guardian’s signature & date

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Printed Name of person who explained consent Signature of Person who explained consent & date

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Printed Witness’ name (if the parent/legal guardian Witness’ signature & date

does not read English)

If you have any questions about this study, please call Dr James at 416 813 6767.

If you have questions about your child’s rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at 416-813-5718.