### SK_THSC-research-ethic2

# Research Consent Form

# (Study participant)

**Title of Research Project:**

Time flow analysis for endoscopic ear surgery.

**Principle Investigator:**

Dr A L 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 surgeon to complete different parts of your 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 ear operation.

If you have had a CT scan for your ear as part of your standard medical care, we would like to use this as part of the study to help us understand how surgical instruments can be designed to fit the shape of the ear better. To do this we would like to take a copy of the CT scan and use it to generate computer models and printed models of the shape of your ear. We will then study this model to see how different surgical instruments can reach inside the ear.

No extra tests or treatments are needed if you take 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 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 you from taking part in this study.

**To society:**

We hope that the information we learn from this study will help surgeons complete ear operations more efficiently in future.

**Confidentiality:**

We will respect your privacy. No information about who you are 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 health record to check on the study. By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your 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 identity.

**Reimbursement:**

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

**Participation:**

It is your choice to take part in this study. You can stop at any time and we will remove your data from the research files on request. The care you get at Sick Kids will not be affected in any way by whether you take 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 any of this money now or in the future because you took part in this study.

If you become ill or are harmed because of study participation, we will treat you 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 taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my 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 medical records will be kept private except as described to me.

6) I understand that no information about who I am 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, to take part in this study.

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Printed Name of Subject & Age Subject’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 subject/legal guardian Witness’ signature & date

does not read English)

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

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