

# Research Consent Form

## Title of Research Project:

Needs Analysis and Time Flow Study to Assess Endoscopic Ear surgery

## Investigator(s):

Dr Adrian Lewis James Principle Investigator 416 813 2191

**Co-Investigators:**

Arushri Swarup Co-investigator 416 813 6767

## Purpose of the Research:

The purpose of this study is to measure the efficiency of the tools used during totally endoscopic ear surgery.

## Description of the Research:

The duration of predetermined steps during cholesteatoma or tympanoplasty surgery will be timed. The number of times it is necessary to change instrument during surgery will also be recorded. Data will be recorded without the identity of the surgeon so it will not be possible to link performance with identity of the surgeon or patient. If you choose not to participate or to leave the study at any time it will have no effect on your employment status.

## 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 is no individual benefit to the participant in completing this study

## To society:

This study aims to benefit otologic surgical practice by identifying limitations in currently available surgical instruments in order to improve instrument design for transcanal endoscopic ear surgery.

## Alternatives to participation:

You may choose not to participate in this study.

## 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. Sick Kids Clinical Research Monitors, or the regulator of the study may see the data to check on the study. By signing this consent form, you agree to let these people look at your data.

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.

This could include external research team members. 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 withdraw consent at any time. Your professional reputation will not be impacted as this study and participants will remain confidential.

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 participate in the study.

During this study we may create new technology that may be worth 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.

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.

**Research Study Results:**

The results of the study intend to be published in an academic journal. If you would like to know the title of the paper please feel free to contact the research investigators.

## 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 agree, or consent, to take part in this study.

Printed Name of Subject & Age Subject’s signature & date

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

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.