

# Research Consent Form

## Title of Research Project:

Otological Instrument User-Feedback Study

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## Purpose of the Research:

The purpose of this study is to collect surgeon feedback on the design of a new otologic instrument developed at the Hospital for Sick Children. The study will consider the use of the new tools in two tasks: A basic bench-top pick-and-place maneuver; and also while using the tools to perform a “mock” surgery with a 3D printed ear anatomy model.

## Description of the Research:

You will be asked to complete questionnaire on the design and operation of the instrument following the completion of the tasks.

Answers to this survey will be used to refine the design of the instruments. No one will know how you answered these questions. If you choose not to participate or to leave the study at any time it will have no effect on your status as an employee or trainee if applicable.

## 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. If the Hospital for Sick Children makes money from the results of this study, you will not be entitled to any of the money.

## To society:

This study aims to benefit neurosurgical practice through the user-centered development of a new otologic instrument that provides greater reach and range-of-motion when performingendoscopic 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. However, SickKids Clinical Research Monitors, or the regulators of the study, may view the survey data. By signing this consent form, you agree to allow these individuals to review 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 information. This group could include external research team members. Following the completion of the research study, the data will be kept as long as required then destroyed as required by SickKids policy.

Published study results will not reveal your identity.

## Reimbursement:

You will not incur any expenses by being involved with this study and therefore no reimbursement is offered.

## Participation:

It is your choice to take part in this study. You can withdraw consent at any time. Your status as employee or trainee will not be impacted in any way. Study participants will remain confidential.

You will be kept informed of any new information that develops during the course of this study that may affect your decision participate. If this happens, we will ask you again if you still want to participate in the study.

Your signing of this consent form does not interfere with your legal rights in any way. The staff of the study, the organizations funding the study, and 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 – Head and Neck Surgery at The Hospital for Sick Children are the sponsors of this study

## Conflict of Interest:

Dr. James Drake 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 status as employee or trainee at Sick Kids if applicable.
4. I am free now, and in the future, to ask questions about the study.
5. I have been told that my study responses 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 or Arushri Swarup

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.