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THE HOSPITAL FOR SICK CHILDREN
Research Ethics Board

# Report on Scientific Peer Review

***PLEASE NOTE – Reviewers must include all substantive issues and/or recommendations on this form, whether or not they have been provided verbally to the investigator.***

## PART A: GENERAL

Primary Investigator: Dr. Adrian James
Co-investigator: Arushri Swarup, MASc. Candidate
Co-investigator: _____
Co-investigator: _____
Co-investigator: _____
Co-investigator: _____

Project Title Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

Funding Agency University of Toronto
Deadline Aug-2018

Brief Description of Project (to be completed by reviewer)

The submitted REB relates to a 2 part study the first part being a survey of otologists regarding their experience of endoscopic ear surgery focused on their view of their own current limitations in adopting the technique and the underlying reasons for this. The second part is an observational study of both the human (surgeon) and equipment related challenges and limitations of endoscopic ear surgery. This study will focus on the work flow and tool use of a number of staff otologist who have variable experience with endoscopic ear surgery beyond a set minimum (1 year). The results of this study will assess the challenges surgeons face in adopting this approach the impact of which will be to inform how best to teach both trainees and experienced surgeons moving forward. It will also assess the opportunity to new equipment design to aid in overcoming some of the current access limitations that exist.

## PART B: BUDGET:

A) Approximate Budget - Year 1 11732.50
B) Is it justified in the application? Yes
C) Are the sums requested adequate? yes
D) Do the items reflect the actual costs of the research interventions, excluding interventions that are part of routine clinical practice? Yes
E) Is there a project contract or agreement (notice of award)? yes

## PART C: REVIEW

Is the hypothesis reasonable? Yes
Is the literature review appropriate? Yes
Is the research protocol clearly described? yes
Is the stated significance of the study plausible? yes
Are the summary pages well prepared? Yes
Are the research methods likely to deliver results to the stated objectives? Yes
Is this study feasible? Yes
If not, why? _____

Is the study likely to yield publishable results? Yes

What is your overall assessment of the application?

This application is well put together and thoughtful in its methodology. Many researchers would have only included the survey portion and I commend the applicants for including the labour intensive observational component which I believe will yield important findings that may impact surgical training, efficiency and ultimately patient outcome.

Please list any specific recommendations (attach an additional page if necessary).

1) In participant recruitment it was initially unclear to me that the PI would be a participant - I was having a hard time adding it up to 5 (3 HSC surgeons + 1 TGH surgeon + PI)
2) Recommend clarifying the role of training in the study is the intention to have the studied surgeons performing the whole operation from start to finish for the designated study surgeries or could residents/fellows participate but metrics just wouldn't be counted during that timeframe where a trainee was operating

**PART D: FOR HUMAN RESEARCH ONLY**

Which of the following prior studies have been published?

Relevant animal studies no

Studies of animals at a stage of development analogous to the subjects of the proposed study no

Relevant adult human studies yes

If the answer to one or more of the above questions is negative, please comment on the feasibility and desirability of undertaking prior studies in animals and/or adult humans before proceeding to a pediatric study.

The current study subjects are otologic surgeons and therefore an animal model is not relevant in this instance. It is likewise not feasible to study otologic surgeons in a model (animal or cadaveric temporal bones) given the importance of scale, disease process and physiologic responses (such as bleeding) to the assesment of surgical efficiency and limitations.

Are patient eligibility and exclusion criteria clearly delineated? Yes

Are the following methods appropriate? Yes

Ascertainment of potential subjects Yes

Making contact with potential subjects Yes

Obtaining consent (if needed) Yes

Is the study comparative? No

Are the study numbers discussed and justified? Yes If yes, are the study numbers sufficient to provide likelihood of an interpretable result? Yes

Are the subjects likely to be enrolled in other studies? No

Is the study descriptive? Yes If yes, is the information to be derived likely to be unique? Yes

Does the study involve disruption of schedules (including school) for subjects/parents? No

If yes, is the disruption justified? _____

Are the potential harms vs. potential benefits appropriate? (For research in children, potential harms must be estimated to be more than balanced by potential benefits; both are quantified in terms of the expected frequency of the harm or benefit, and the magnitude of the harm or benefit) Yes

If this is a clinical trial comparing two or more treatment regimens, are the risk - benefit ratios of each regimen well balanced so that the average expert would not favour one regimen over the other (ie., equipoise exists)?

Yes _____ No _____ Don't Know _____

Is statistical analysis required? Yes If yes, is there a discussion of statistical methods and are they appropriate? Yes

Is the plan for monitoring safety and efficacy (in the case of diagnostic or therapeutic trials) of the human subjects appropriate? yes

For clinical trials (diagnostic as well as therapeutic), is the plan for monitoring safety and if relevant, efficacy, appropriate? (see attachment for categories of research and the monitoring matrix) Yes

Should extra-mural scientific peer review be obtained (e.g., for conflicts of interest of the researchers, the institution, and or the internal peer reviewers; for questionable risk - benefit ratio; for serious threats to the privacy of human subjects)? No

Are there any major changes that need to be made before this proposal should be submitted for ethical review? _____

see above minor recommendations/clarifications of protocol

Assuming that this committee will accept any changes made to the protocol, is scientific merit including significance of the study adequate to justify its ethical consideration? yes

**PART E: RANKING**

Please rank the proposal as is, and the proposal if the proposed revisions are made.
Please use the two digit CIHR rating system: 4.5 - 4.9 outstanding, 4.0 - 4.4 excellent, 3.5 - 3.9 very good, 3.0 - 3.4 acceptable, but low priority, 2.5 - 2.9 needs revision, 2.0 - 2.4 needs major revision, 1.0 - 1.9 seriously flawed, 0 not acceptable.

| Reviewer | Signature | Scientific Discipline | Proposal As Is | Proposal after Revisions Made |
|---|---|---|---|---|
| **Sharon Cushing** | | **Otolaryngology Head and Neck Surgery** | **4.4** | **4.4** |

Date of Review: November 20, 2016

| disciplines involved in research | disciplines of investigators | disciplines of scientific reviewers |
|---|---|---|
| Otolaryngology Head and Neck Surgery | Otolaryngology Head and Neck Surg | Otolaryngology Head and Neck Surg |
| Biomedical Engineering | Biomedical Engineering | |
| | | |

**PART F: ITEMIZED RESPONSE**

An itemized written response to all the issues raised by the reviewers noting where revisions were made in the revised protocol must be provided to the Research Committee Review Chair/Grant Review Committee Chair for final approval & signoff prior to submission to the REB for ethical approval.

Final Approval of Research Director/Committee Chair: _____
Date: _____

**PART G: CONFLICT OF INTEREST DECLARATION (for reviewers):**

Please confirm with your signature that all contracts and any conflicts of interest (actual, apparent, perceived, or potential)* relating to this project are disclosed to the Manager, Research Contracts for review.

Signature_____

* Conflicts of interest include but are not limited to the following situations:
Do you or any of the involved staff members or your/their dependents have,
(1) employment or consulting arrangements and/or a financial interest in the sponsor of the study, or with proposed subcontractors, vendors, or collaborators;
(2) a financial interest in the product/medical device that is the subject of the study?