

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)

~~This project aims to understand the current barriers to endoscopic ear surgery and better characterize what technologic advances could improve the ease with which endoscopic ear surgery is adopted and performed. The project is split into two stages. The first stage involves a needs assessment based on a survey of the international otologic community to document issues with endoscopic ear surgery techniques, with a specific focus on identifying issues with existing surgical instrumentation for endoscopic ear procedures. The second stage involves a time flow study of endoscopic ear surgeons documenting the time required for each surgical step, and the number of times the surgeon changes the operating instrument. Both stage one and two aim to identify the current limitations of endoscopic ear surgery tools and the better understand the need for technologic advancement in this field.~~

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)? no

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?

I feel this a timely and worthy study with the potential to have a significant clinical impact within the field of endoscopic ear surgery.

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

none.

PART D: FOR HUMAN RESEARCH ONLY

Which of the following prior studies have been published?

Relevant animal studies n/a

Studies of animals at a stage of development analogous to the subjects of the proposed study n/a

Relevant adult human studies n/a

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.

not applicable; observational/descriptive study only.

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? yes

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? yes

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) no potential harms

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 _____ **NOT APPLICABLE** ✓

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? n/a

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) n/a

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)? n/a

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


no

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
Jane Lea		Otolaryngology	4.0	4.0

Date of Review: November 30th, 2016

disciplines involved in research	disciplines of investigators	disciplines of scientific reviewers
otolaryngology	otolaryngology	otolaryngology
engineering	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  Nov 30th, 2016

* 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?