

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, MSc. 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 assessment 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

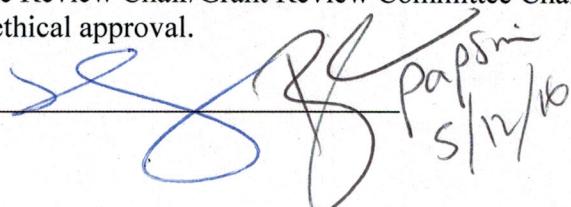
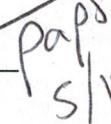
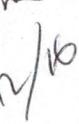
disciplines involved in research	disciplines of investigators	disciplines of scientific reviewers
Otolaryngology Head and Neck Surgery	Otolaryngology Head and Neck Surg	Otolaryngology Head and Neck Surc
Biomedical Engineering	Biomedical Engineering	

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.

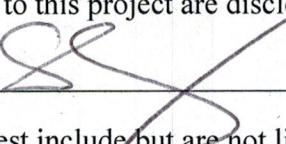
Final Approval of Research Director/Committee Chair:

Date: Dec 05/16

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?

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:

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

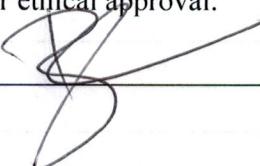
Date of Review: November 30th, 2016

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: 5/12/16



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?

Response to Scientific Peer Review by Dr. Sharon Cushing - Please see the highlighted sections where specific recommendations were added.

Study Design (General Overview):

The time flow analysis will be recorded by the MSc student during ear surgery. The surgery will be divided into steps, described in the data collection form located in Appendix B. The type of instruments used during the different steps and the number of changes between instruments will also be noted. These observations will lead to an appreciation of the ergonomic requirements of instruments and the design advantages of different instruments for specific maneuvers. The time taken for five surgeons to perform ten surgeries each will be recorded. Each step for each surgeon will have a mean and standard error time, and statistical difference between surgeons for each step will be calculated. This will aim to determine the inefficiencies and address the steps where further instrument design would be beneficial. This would also provide a good benchmark against which to measure efficiency and feasibility of future tools that would be developed.

Participants

The time flow study will include two kinds of participants: patients, who will be undergoing ear surgery, and surgeons, who will be performing the ear surgery.

Participant Recruitment

The PI's colleagues in otolaryngology are interested in this project and would also like to improve their experience with TEES. Three additional surgeons from SickKids and one from Toronto General Hospital have expressed interest in participating in this study.

Inclusion criteria

Patient participants: 40 surgical patients, who require cholesteatoma surgery or tympanoplasty (surgical repair of perforated ear drum).

Surgeon participants: 5 surgeons with more than one year of experience in endoscopic ear surgery. The PI, three additional surgeons from SickKids and one surgeon from Toronto General Hospital will be asked to participate.

Comment [AS1]: Recommendation 1:
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)

Exclusion criteria

Residents and fellows who are in training. It would be inappropriate to include surgeons in training in the study as their lack of experience will contribute to delays and lack of efficiency in time flow, so confounding the estimate of the contribution of instrument design to surgical time flow. Although the ability of trainees to use different instruments in TEES and the impact of their level of experience on this ability would be of interest, they are beyond the current scope and design of this study.

Study intervention

Each surgeon will be observed and recorded performing ten operations. The steps that are recorded will be performed by the experienced surgeon who has given consent for the study. The time and number of instruments changed will be recorded for the steps outlined in the Data Collection Form, included in Appendix B.

Outcome measures

The following outcomes will be measured: duration of the surgical steps described above and the number of times the surgeon changes the tool he/she is using during the step.

Statistical analysis

The factor to be studied is the type of instruments used for each surgical step. The block is the surgeon. The response is the time required for the surgical step. Therefore, an ANOVA will be used to determine if there is a statistical difference in the time to complete a surgical step depending on the instruments used.

Ethical concerns

The identity of the surgeon will not be linked to the time flow data, to ensure there is no risk of participant embarrassment regarding surgical efficiency compared with peers.

Budget

The total budget is given in the table below.

Personnel	Description	Price/Unit	Unit	Qty	Total Cost
Master's Student	Stipend	23465	year	0.5	11732.5

Since this study is observational, it just requires the time of the Master's student to conduct the study.

Participant Consent

Patients who are eligible for TEES during their surgery will be asked to fill out a consent form or assent form depending on their capacity.

Comment [AS2]: Recommendation 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