February 7, 2017

Dr. Adrian James
Otolaryngology
Hospital for Sick Children

Dear Dr. James,

Re: Your study "Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery".
REB File No. 1000055626

The above named study was screened by the Research Ethics Office (REO).

The following issues were noted:

1. Please remove the appendices from all applicable study documents (i.e. “Appendix A”).

2. **Protocol**

a) Please revise all references to appendices to the name of the study document.

3. **Preliminary Interviews of Local Otolaryngologists**

**As per page 2 of the research study protocol:**

*“Preliminary interviews of local otolaryngologists, with varied experience in TEES within the University of Toronto, will be conducted by an IBBME MASc student (Arushri Swarup). Questions will ask for comments on factors that have prevented otologists from using endoscopes in ear surgery, and for comments on the perceived strengths and weaknesses of currently available instruments for endoscopic ear surgery. Their opinions will be de-identified and collated to develop a list of requirements for improvements in instrument design”.*

a) Please provide the recruitment and consent plan for local otolaryngologists that will be invited to take part in this phase of the research study.
b) Please provide the consent forms that will be used to obtain consent from local otolaryngologists for the preliminary interviews that will be completed for the needs analysis portion of this study.
c) Please provide the interview script that will be used for this portion of the research study.

4. **Responses to Internal Science Review**

a) Please provide the Board with the itemized responses to the reviewers’ questions that were raised during the internal scientific peer review that was completed for this research study.

5. **Time Flow Study**
   As per page 4 of the research study protocol:

   *"Five 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".*

a) Please clarify if the study PI (Dr. Adrian James) is also a study participant. If so, please provide the rationale for including the study PI as a participant and whether this will affect the integrity of the study data.

6. **Recruitment Material for Healthcare Professionals**

a) Please ensure that all of the recruitment material (i.e. email script/invitation, survey landing page, etc..) contain the following sentence:
   *"Your participation or nonparticipation in this survey will be unknown and will not affect your professional status and/or integrity in any way".*

b) Please confirm that written consent will be obtained from each of the respective medical societies prior to sending the invitation email to their professional members.

7. **REDCap Data Collection Forms**

a) Please provide the final version of the REDCap data collection forms that will be used for this research study.

8. **Master Code Breaking File**
   As per page 3 of the study protocol:

   *"In order to ensure that results of the survey remain de-identified, all contact information will be kept in a separate password protected spreadsheet from the results of the survey".*

a) Please provide the Board with the master code breaking file that will be used to keep all identifiable information separate from the study data.

9. **eREB Application**

a) **Section 16: Recruitment of Patients** - Please note that the initial contact with potential participants (and/or their caregiver) should come from an individual that is within the patient's circle of care (Article 3.1 TCPS 2, 2014).

   If the patient (and/or their caregiver) is interested in hearing more about the research study, they would then be approached by a member of the research team to further discuss the research study and obtain the appropriate consent (if the participant and/or their caregiver agrees).

   Please revise this section of the eREB application form accordingly.

b) **Section 24: Access to Kidcare for Research Purposes**
Please specifically clarify how information that will be obtained from Kidcare will be accessed and utilized for your research study. Please complete and upload the KidCare SOP within the SickKids eREB for this ethics submission. Please visit the following website for more information: http://my.sickkids.ca/research/clinical-research-services/research-ethics/Pages/Forms-and-Templates.aspx

The Board requests a response to the following issues related to consent/assent:

1. Please list the full first and last name of the Principal Investigator within the first page of the consent & assent forms.

2. Last Page of Consent - Please add the name and contact information for participants to call if they have any questions pertaining to this research study:

   *"If you have any questions about this study, please call [insert name] at [insert contact information]"*

3. **Surgeon Consent** – Please add the following sentence to this consent form:
   *"If you choose not to participate or to leave the study at any time it will have no effect on your employment status".*

4. **Surgeon Consent** – Please remove "Template" from the header region of this consent form.

5. **Parent Consent** – Please remove the following wording from the header region of this consent form: "Parent or carer of participant" and replace with "Parent/Legal Guardian".

6. Please ensure that the study title listed on the first page of the consent & assent forms is harmonized with the study title that is listed within the first page of the study protocol and eREB application form.

7. **Research Study Results -** Please include a sentence stating how the results of your research study will be made available for participants.

   ****Please ensure to reference the above REB file number on all correspondence related to this study. Additionally, all documents should be revised showing track changes and the version date should be updated prior to re-submission. Please include clean and tracked change copies of all revised study documents****

I am available to work with you to resolve the outstanding issues. If the issues cannot be resolved satisfactorily, you may be invited to a meeting for further discussion. Please initiate contact with me as soon as possible to discuss the changes. If we do not receive a response from you within 90 calendar days, your study will be withdrawn. If this occurs, you will need to submit a new application to the REB for review.

Once the issues identified have been resolved, the REB will continue with the review your research study. Please note these steps are required before the review of your study can continue.

Yours truly

Ryan Singh
Coordinator, Research Ethics Office
Phone: 416.813.4985 (internal ext. 204985)
Fax: 416.813.6515
e-mail: ryan.singh@sickkids.ca