Project Title: Tolerance of nasopharyngoscopy post-administration of unflavoured versus flavoured aerosolized lidocaine.

Principal Investigator: Jason A. Beyea, MD PhD FRCSC. Department of Otolaryngology, Queen’s University.

Letter of Information

1. Invitation to Participate

You are being invited to participate in this study investigating whether the flavour of lidocaine can improve the tolerability of undergoing a nasopharyngoscopy examination.

2. Purpose of the Letter

This letter is meant to provide you with the information needed for you to make an informed choice regarding participation in this research study.

3. Purpose of this Study

This study is being done to investigate whether flavoured lidocaine is effective in improving patient satisfaction and ease of performing a nasopharyngoscopy examination of the nose, mouth, and voice box.

Currently, unflavoured lidocaine can be unpleasant for patients undergoing the procedure. Although lidocaine can minimize pain, the unpleasant taste is a concern. This study is expected to yield valuable information to guide the use and adoption of flavoured lidocaine as a means to reduce patient anxiety, increase patient satisfaction, and reduce the likelihood of needing to stop the examination early.

4. Inclusion Criteria

Individuals above the age of 18 who require a nasopharyngoscopy examination at Kingston Health Sciences Otolaryngology - Head & Neck surgery clinic are eligible to participate in this study.

5. Exclusion Criteria

Individuals who had a previous allergic reaction to flavouring agents or are under age 18 are not eligible to participate in this study.
6. **Study Procedures**

If you agree to participate, you will be asked to complete a survey at the end of your nasopharyngoscopy examination. At the start of the study, you will be randomized to obtain either flavoured or unflavoured lidocaine by flip of a coin. If selected to obtain the flavoured lidocaine, you will be asked to select from a choice of 10 flavours. The lidocaine will be sprayed in your nose and the scope will be completed by your Otolaryngologist-Head and Neck Surgeon. You will then be asked to complete a questionnaire about your experience with the lidocaine anesthetic along with the nasopharyngoscopy procedure.

This study will be conducted in Hotel Dieu Hospital. There will be approximately 58 participants in this study.

7. **Possible Risks and Harms**

The primary risk of this study is an allergic reaction to the flavouring agent provided with your lidocaine anesthetic. The risk of an allergic reaction is less than 1.4%. A medical team including a physician and nurses will be on the premises at all times in case a medical complication were to arise.

8. **Possible Benefits**

It is possible that participation in this study can help alleviate some of the discomfort of undergoing a nasopharyngoscopic examination and improve the likelihood of a successful examination.

Furthermore, by participating in this study you are helping physicians and researchers improve the process of administering a nasopharyngoscopic exam to other patients in the future.

9. **Compensation**

You will not be compensated for your participation in this research.

10. **Voluntary Participation**

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your current or future care.
11. Confidentiality

All data collected will remain confidential, stored in a locked office, and accessible only to the investigators of this study. If you choose to withdraw from this study, your data will be removed and destroyed. If the results are published, your name will not be used and you will not be identifiable.

Representatives of the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may contact you or require access to your information to monitor the conduct of this research.

12. Contacts for Further Information

If you require further information regarding this project or your participation in this study, please contact Dr. Jason Beyea (Principal Investigator) at (613) 544-3400 ext.3620 or jason.beyea@kingstonhsc.ca

For ethics concerns please contact the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Call 1-844-535-2988 (toll free in North America) or email the HSREB Chair at clarkaf@queensu.ca

13. Publication

If the results of this study are published, none of your identifying or contact information will be used. If you would like to receive a copy of any potential study results, please provide your name and contact information on a piece of paper separate from the Consent Form.

14. Consent

Enrolment in this study is conditional on your written, informed consent. If this study has been explained to your satisfaction, and you would like to participate, please find the Consent Form attached.

This letter is yours to keep for future reference.
Consent Form

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Study Investigator’s Name: Jason A. Beyea, MD PhD FRCSC. Department of Otolaryngology, Queen’s University, Kingston, ON.

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant’s Name (please print): __________________________________________

Participant’s Signature: __________________________________________

Date: __________________________________________

Person Obtaining Informed Consent (please print): __________________________

Signature: __________________________________________

Date: __________________________________________