Official Title:	Computational Cranial and Cervical Muscle Network in Normal and Disordered Voice
NCT Number:	NCT04713033
Study Number:	20-01770
Document Type:	Informed Consent Form
Date of the Document:	• December 22, 2020

Research Subject Informed Consent Form (Control Group)

Title of Study:	Development of a Visual Database of Vocal Tract Dynamics and Vocal Fold Kinematics in Professional Vocal Athletes across Vocal Styles s20-01770
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether you want to take part in this study. People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to improve our understanding of how the vocal tract and the muscles of the larynx and the head work at baseline and after vocal fatigue. In this regard, we are creating a voice-specific tracking system. You have been asked to take part in this study because you are a vocally healthy volunteer and you will participate in the study as a control.

3. How long will I be in the study? How many other people will be in the study?

Your participation in the study will be 3 visits total. A total of 90 participants will be enrolled in the study at NYULH.

4. What will I be asked to do in the study?

If you agree to take part in this study, you will undergo:

1. a laryngoscopy examination (15min)
2. an surface electromyogram (sEMG) examination of your head and neck region (30min)
3. have your speaking and singing voice recorded and analyzed. (15min)

The laryngoscopy examination will be conducted at the NYU Voice Center during today's visit. During the laryngoscopy procedure, we will video record your throat using a procedure called videostroboscopy and/or high speed video. As part of this procedure we will numb your nose and throat with lidocaine spray and then we will insert an endoscope (a tube or rod with a camera attached) into your nose or mouth to look at your throat.

We will ask you to say "eee" and sing a few bars of a song that represents your vocal style or genre of choice. While you do these tasks, we will identify and track changes in your vocal cords. You may also be asked to do these same tasks while we record your voice using standard acoustic recording equipment available at the NYU Voice Center and while having some electrode stickers attached to your neck area. This is called EMG and measures the electric signals that your muscles produce while you phonate. For these audio recordings, you hold out a vowel, read sentences, provide a one-minute speech sample on a neutral topic, and sing a common song.

After baseline measurements, you will be asked to read a passage in the presence of intense background noise. The duration of reading that induces self-perceived vocal fatigue varies among vocally-healthy individuals. Therefore, we will use a questionnaire adapted for vocal effort to have you rate your effort while reading the first section of a text called "The Rainbow Passage" at up to four time points during the load task: at baseline and again after 30, 45, and 60 minutes of reading.

After this process that lasts about an hour, you will be asked to record the same acoustic measurements as before, while wearing the same electrodes on your skin.

You will be asked to come back for another two visits to have your voice measured in the same way, one two weeks after the baseline visit and one two months after the first visit.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Risk related to laryngoscopy

This procedure involves the use of topical nasal sprays and passage of an endoscope. The purpose of the topical nasal sprays are to reduce any discomfort when passing the camera through your nasal cavity.

The use of oxymetazoline and lidocaine nasal sprays involves a small risk of self-limited nasal bleeding and an extremely low risk of an allergic reaction. The risks of the endoscope include minor nasal discomfort, self-limited nasal bleeding, and gagging. Vasovagal reactions (a sudden drop in blood pressure that can lead to paleness, nausea, sweating, a rapid heartbeat, and fainting) do occur, but are extremely rare.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about your information being used in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

Information obtained from the study can help clinicians better understand vocal tract and voice box movement and function during vocal fatigue (e.g. excessive speaking or singing) to guide treatment for vocally impaired patients with a condition called muscle tension dysphonia or patients with paralysis of the vocal fold in the future. However, there are no direct benefits to you for participating in the study.

8. What other choices do I have if I do not participate?

The alternative is to not participate in this study. This will in no way affect your present or future care at NYU Langone Health. Will I be paid for being in this study?

We will pay you $20/hour of participation. You are expected to participate in research activities for a total of 6 hours during all visits and receive up to $120 for your time.

9. Will I have to pay for anything?

There are no expenses or costs to you for taking part in the study.

10. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. If such complications arise, the principle investigator(s) will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury–related costs. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

11. When is the study over? Can I leave the Study before it ends?

Your direct participation in the study will be over once you have taken part in the laryngoscopy and/or MRI procedure(s). The overall study is expected to end after all participants have been recruited to the study and all participant information has been collected. However, the principle investigator could end your participation in the study earlier if he feels it is necessary for your health or safety. Although highly unlikely,

the principle investigator or other individuals responsible for monitoring the safety of the study may also stop the study if they deem the study unsafe.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

12. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- Funding Source: National Institutes of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the

principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

13. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies, including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

14. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date