

**UNIVERSITY OF WISCONSIN-MADISON**  
**Subject CONSENT to Participate in Research**  
**And**  
**AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research**

**Title of the Study:**

Anatomic-acoustic correlates of the developing vocal tract: An imaging and acoustic study

**Principal Investigator:**

Houri K. Vorperian, Ph.D. (phone: 608-263-5513) (email: [vorperian@waisman.wisc.edu](mailto:vorperian@waisman.wisc.edu))

**Mailing Address:**

Vocal Tract Development Laboratory, Room 427, 1500 Highland Ave, Madison, WI 53705

**INVITATION**

If you are a parent/ legal authorized representative, please read “you” as “the participant”.

You are invited to participate in this Speech Production research study. This study is about how the measurements of the vocal tract (i.e. mouth and throat) are related to a person’s speech sounds. This study also looks at how such relationships are similar or different in people with and without developmental disabilities, like Down syndrome or cerebral palsy.

It is your choice to participate in this study. If you choose not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates – the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation – will not be affected in any way.

**A. WHAT IS THE PURPOSE OF THIS STUDY?**

The goal of this study is to find out how the size of different parts of the vocal tract change as people grow and how those changes affect speech sounds. Also, to find out how such changes are similar or different in people with and without developmental disabilities.

**B. WHAT WILL MY PARTICIPATION INVOLVE?**

If you choose to participate in this research study, you will be asked to do one or more of the following:

1) Allow our study staff to use your previous or upcoming MRI or CT scans. We will use it to measure the different parts of your mouth and neck.

Check here to give permission to release your completed or upcoming CT or MRI study of the head and/or neck to our Vocal Tract Development Lab.

If you have checked the box above, please specify the type of study you want to release by checking one or both boxes below.

Medical CT or MRI study (*Note: You will still need to fill out and sign a Medical Release form from the hospital or clinic where your images were taken*).

CT or MRI study for research. *Please indicate the source of your CT or MRI study by checking a box below:*

MRI Neck Anatomy of Adult Individuals (Greg Avey, M.D.)

- 2) Share some of your health information (such as your height and weight) with our study staff during your first study visit.
- 3) Have the choice to get a hearing screening. This means you will listen to beeps in a quiet designated research room. If you request it, you may get a copy of the results. If you do not pass the hearing screening, you will get a referral to an audiologist. It will be your choice to follow up on the referral.
- 4) Be recorded while you hold out sounds like “ee” and “ah” and repeat some words and sentences, and have a short conversation. You will do this while you are sitting up, and possibly while lying down. All participants have the option to agree to participate in this research study in the future; we will ask you at the end of the consent form whether or not you agree to be contacted to participate in this study again.

**Adults and typically developing children:** this should take about 20-30 minutes.

**Children with a developmental disability or any participant who enrolls between birth and two years old:** For young children, it may be most suitable to do audio recordings at your home. Each recording session will last 30-60 minutes. The total number of sessions will depend on your child’s age when he/she begins the study and/or data needs of this study. Ideally, we would like to take several recordings at specific times during development and if you agree to be contacted in the future, we may do so as specified below:

- One month to age two to age two.*** We will do audio recordings every three to four months. We will record your child making sounds, like cooing and babbling, or saying words while your child is playing and interacting with you.
- Between the ages of two and five years old.*** We will record your child one time every six months. We will use toys and pictures to get your child to say specific words and sentences.
- Six years old and older.*** We will record your child once per year. We will use toys and pictures to get your child to say specific words and sentences.

- 5) Breathe into a tube while sitting up and possibly while lying down (***for participants age three years or older***). This part of the study will last 30-45 minutes. A clean and sterilized tube will be used for each person that participates in this study. We will ask you to take a deep breath in, hold your breath for about 1 second, and then breathe out slowly and deeply. The computer will start recording as you breathe out and you will hear some clicking sounds. We will record your breathing into the tube while you are sitting in a chair, and we may also record you while you are lying down. The purpose of this is for the computer to measure the size of your mouth and throat using sound energy. You can take as many breaks as you need. You may also choose to stop the test at any time. Your participation will be based on your age, as described in point number four above.

**We will also collect the following information about you for this research study:**

From you:

- Birth date, address, phone number, email address
- Speech, language & hearing history and parental/guardian intelligibility rating as well as medical history important for speech including surgeries.
- Speech recordings

From your medical records, health records (such as x-rays, copy of audiogram), and/or billing records if applicable, such as your height and weight, at time of your imaging study (MRI and/or CT).

### **C. ARE THERE ANY BENEFITS TO ME?**

You will not benefit directly from choosing to participate in this research study. However, your choice to participate in this research study will help us learn more about how vocal tract measurements affect speech development. This information will benefit other people in the future.

### **D. WILL I BE PAID FOR MY PARTICIPATION?**

You will be paid for participating in this study. Payment amount depends on the number of tasks and the number of visits completed. Participants who give a speech sample only will receive \$15 or a gift of equal value. Participants who give a speech sample and either breathe into a tube or give a release for his/her imaging study (head or neck CT or MRI done for other reasons) will receive \$25 or a gift of equal value. Participants who give a speech sample, breathe into a tube, and sign a release to access their imaging study will receive \$35 or a gift of equal value.

### **E. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?**

There are no significant risks or major discomforts associated with this study. It does, however, require that you sit still during the recordings and the hearing screening. We take all precautions to keep participant information confidential. However, there is a small risk that your study information may become known to someone who is not on the study team. Speech recordings have been used in other studies for over 70 years with no danger or complications. However, many people feel awkward or self-conscious while being recorded. Home visits may occur as part of this study if requested by guardian/parent. If child or elder abuse or neglect is observed during a visit, members of the study team may be required by state law to report this to the appropriate authorities. This may include reporting to the local law enforcement or protective service agencies, resulting in legal or social risks to you or other members of your household. Your confidentiality cannot be guaranteed in cases of child or elder abuse.

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Hourii K. Vorperian at 608-263-5513 if you are injured or for further information.

### **F. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?**

If you agree and choose to be in this study, we will assign you a code (a letter with a number code e.g. F25) and your images, speech recording and all measurements will be stored using that code to keep your privacy. The radiology physicians who are assisting us in this study may also keep a list with a link between your name and your assigned code.

We take great care to protect the identity of all our research participants. We use the code assigned to each participant to store data NOT your name. All research data are stored in locked cabinets or password-protected computers in a locked room that is accessed only by study personnel. Select speech recordings may be chosen for perceptual ratings of the quality and intelligibility by adult volunteers. These volunteers will not have knowledge of your identity in relation to your speech recordings. The data collected in the course of this research may be used in research reports and papers published in scientific journals or may be presented at scientific meetings. Information or findings from this project that is to be shared with non-study members or the scientific community will not have any identifiable information (such as your name). Recordings will be destroyed 7 years after the publication of our results in a scientific journal or book.

Vorperian, Anatomic-Acoustic Correlates of the Developing Vocal Tract:  
An Imaging and Acoustic Study, October 4, 2016

The information collected from you during this study and from your medical records will be used for this study by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation). We will share coded data and images with a research collaborator outside of the UW-Madison.

**The ‘others at UW-Madison and its affiliates’ who may need to use your health information in the course of this research include:**

- UW-Madison regulatory and research oversight boards and officers.
- Accounting and billing personnel at the UW-Madison

**The ‘others outside of UW-Madison and its affiliates’ who may receive your health information in the course of this research include: NONE**

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. This study, however, DOES NOT involve sharing any of your health information with individuals outside the UW-Madison and its affiliates.

### **G. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?**

Your permission is voluntary. You may choose not to sign this form. If you refuse to sign this form, you cannot take part in this research study. However, if you sign this form but change your mind, you may request to stop the study at any time.

**IF YOU DECIDE TO NOT PARTICIPATE IN THIS STUDY, OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES WILL NOT BE AFFECTED IN ANY WAY.**

### **H. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?**

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. There is no end date for the use of your health information for this research study unless you withdraw your permission in writing. You may withdraw your permission to stop the use of your health information at any time by writing to:

*Houri K. Vorperian, Ph.D.*

Vocal Tract Development Laboratory, Room 427, 1500 Highland Ave, Madison, WI 53705

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

### **I. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?**

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator, Hourı K. Vorperian, Ph.D. at (608) 263-5513. For information on the rights of research subjects, you may contact the UW Hospital and Clinics Patient Relations Representative at (608) 263-8009.

**AGREEMENT TO PARTICIPATE IN THIS STUDY**

**AND**

**PERMISSION TO USE AND/OR DISCLOSE MY CHILD'S HEALTH INFORMATION**

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use my/my child's health information as described above.

Check here if we may contact you for future participation in this research study on the development of speech production.

What is the best way to contact you? \_\_\_\_\_

Check here if we may **NOT** contact you for future participation in this research study on the development of speech production.

**Name of Participant (please print):** \_\_\_\_\_

\_\_\_\_\_  
Signature for Minors age 15-17

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Participant/Parent/Guardian  
or Legal Authorized Representative

\_\_\_\_\_  
Date

**YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.**

**Signature of person obtaining consent and authorization:**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date