

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

From Ultrasound and MRI to articulatory and acoustic models of child speech development

Your child is invited to participate in a research study of how kindergarten and elementary school children produce speech, and how their productions develop over the course of a three-year period. Your child was selected as a possible subject because you responded to an advertisement for the study. We ask that you read this form and ask any questions you may have before agreeing to allow your child to participate in the study.

The study is being conducted by Professor Steven Lulich and members of the Speech Production Laboratory at the Indiana University Department of Speech & Hearing Sciences.

STUDY PURPOSE

The purpose of this study is to investigate how children aged 5-9 produce speech against the backdrop of rapidly changing/growing vocal tract anatomy. Little is known about child speech production in general, and even less is known about factors involved in longitudinal speech development. This study will provide much-needed empirical data which will be used to model and better understand child speech production and development.

In order to study the development of speech over time, we are collecting data in one MRI session and one to three speech sessions each year for 3 years.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree for your child to participate in this study, your child will be one of 21 subjects participating in this research each year for 3 years. The 21 subjects will be divided into three age groups, with starting ages of 5, 6, and 7 years.

ELIGIBILITY CRITERIA

Children who are native or near-native speakers of American English **are eligible** to participate. "Near-native" means age-appropriate proficiency and with no recognizable foreign accent, as determined by the parent/guardian.

Children with metal in their mouths, such as permanent retainers or palate expanders, **are not eligible** to participate in this study.

Children with a diagnosis of Developmental Language Disorder (also known as Specific Language Impairment), Developmental Apraxia of Speech, or Developmental Speech Delay **are eligible** to participate. Children with no speech-language diagnosis **are eligible** to participate.

Children who did not begin the study in one of the 5, 6, or 7-year-old age groups **are not eligible** to participate.

Children who do not successfully complete the MRI session in the first year **are not eligible** to continue in the study.

PROCEDURES FOR THE STUDY:

If you agree for your child to participate in this study, you and/or your child will be asked to do the following things:

MRI Session:

1. You will fill out a safety questionnaire provided by the Imaging Research Facility at Indiana University, which will be used to determine whether your child can safely participate in this study.
2. You will fill out a brief “longitudinal key” so that your child’s data from year to year can be grouped together and not confused with another child’s data.
3. Your child’s standing height and weight will be measured using a stadiometer of the sort that you may have seen in a doctor’s office.
4. Your child will be familiarized with the MRI setup using a mock MRI machine.
5. Your child will be positioned within the real MRI machine and asked to lie still for approximately 6 minutes while watching a short video. During this time, the MRI machine will image your child’s vocal tract. The total duration of time that your child will be in the MRI machine is expected to be less than 15 minutes.

Speech Session(s):

6. You will fill out a brief “longitudinal key” so that your child’s data from year to year can be grouped together and not confused with another child’s data.
7. Your child’s standing height, sitting height, and weight will be measured using a stadiometer of the sort that you may have seen in a doctor’s office.
8. We will make an impression of your child’s palate using standard dental impression materials.
9. We will make recordings of your child’s speech while repeating words and sentences, and telling short stories about picture sequences. These recordings will be made using a microphone, a webcam, and an ultrasound transducer.
 - a. The microphone will be situated on a stand in front of your child. The microphone will record your child’s speech, which is directly related to the acoustic properties of the vocal tract.
 - b. A webcam will be used record video of your child’s face on the right side. The video will focus on the region around the lower jaw and chin, the lips, and the lower portion of the nose.
 - c. An ultrasound transducer will be used to image tongue motion. The transducer will be manually held under your child’s lower jaw/chin by one of the investigators. A layer of water-based gel is necessary between the transducer and your child’s jaw/chin in order to ensure optimal image quality.

Depending on your child’s attention span and ability to comply with investigators’ instructions, one, two, or three Speech Sessions may be necessary. The investigators will make every effort to keep the number of Speech Sessions to a minimum.

In addition to periodic breaks that we have included in the design of this experiment, your child may take a break at any time. We anticipate that the entire recording session will take between 135 and 225

minutes (2 hours 15 minutes – 3 hours 45 minutes), depending on the number of Speech Sessions needed.

Your child's data may be shared with other researchers, but only after all identifying marks and labels have been removed.

RISKS OF TAKING PART IN THE STUDY:

MRI is routinely used in clinical practice and is considered to pose no more than minimal risk to your child's health or safety. Nevertheless, MRI machines produce powerful magnetic fields that can suddenly turn ordinary magnetic objects into very dangerous "missiles" if they are brought close enough to the MRI machine. Such objects can cause serious injury or death to individuals near or in the MRI machine. The safety procedures established by the Imaging Research Facility are meant to prevent such instances by ensuring that magnetic objects are not brought into the MRI room. In case of emergency, the magnetic field can be quenched immediately and individuals within the MRI room can be evacuated quickly.

There is a risk of some anxiety or claustrophobia due to being inside a close space during the MRI scan. The process of familiarizing your child with the mock scanner is meant to mitigate anxiety and also to assess whether your child will likely be able to tolerate being inside the real MRI machine.

Additional risks and discomforts associated with MRI scanning are:

Completing the MRI Safety Screening Form: You or your child may be uncomfortable completing the interview. For instance, there are questions about the existence of tattoos and piercings, and their locations, on the body.

The MRI scan: We will perform structural scans of your child's head and neck. It is possible to 'reconstruct' the head and show some of the facial features of the participant, and there is a very small risk of potential lack of confidentiality. While these data will be publicly archived for sharing with other researchers, no identifiable information will be included in the archive, and no identifiable information will be included in publications or teaching materials derived from these data.

This MRI scan is not a medical test. It is designed to address research questions and it is not a complete scan for any clinical purpose. If there were to be an abnormality, the scan, the MRI technician, or the researcher might not detect it. If the MRI operator or investigator suspects a possible abnormality, the scan will be sent without any participant identifiers to a neuroradiologist for further review. If the neuroradiologist recommends further action, you will be notified by the principal investigator of the study.

The MRI scanner: Lying in the MRI scanner can provoke discomfort for some people who are claustrophobic, as the MRI scanner itself is a long narrow tube, and some people can find it confining.

MRI has not been shown to produce health problems in normal, healthy individuals. The MRI scanner does not produce ionizing radiation, which is radiation associated with conventional radioactive sources, such as radioactive iodine, uranium, or other substances. No medication, needle stick, or injections of drug or contrast agents are involved. There are hundreds of imagers

of this type used in the U.S. and abroad, both to assist doctors in clinical diagnoses and for research. To view a copy of the Food and Drug Administration safety guidelines for MR imagers, simply ask the MRI operator.

Because of the strong magnetic fields used for MRI scanners, persons who have magnetic life-support devices (e.g., pacemakers and aneurysm clips), metal prostheses or other metallic objects (e.g. cochlear implants, steel pins implanted to help repair and strengthen broken bones, metal fragments from previous injuries) cannot participate in this research.

While there is no evidence of increased risk with multiple scans, the risks associated with multiple scans are not known. The Imaging Research Facility at Indiana University (Bloomington), in conjunction with the Institutions Review Board at Indiana University, has adopted an arbitrary maximum of 40 hours of scanning time per individual per year, and the time involved in the present study is well below that limit.

Ultrasound is often used to see internal body structures such as the heart (echocardiography). There are no known side effects associated with this type of ultrasound examination, and it causes no physical discomforts. It is possible that your child may feel some slight discomfort from remaining seated and/or wearing the ultrasound headset for a long period of time. Ultrasound involves no radiation exposure.

There is a risk of some anxiety and/or gagging due to the palate impressions. Palate impressions are easy and safe to make, and they are routinely performed in this kind of research as well as in dentists' offices. If your child is unable to complete a palate impression or if your child begins to gag, it is possible to remove the impression material quickly.

There is always a possibility of loss of confidentiality in a research study, but the risk is minimal and every possible precaution will be taken to avoid this risk. The only identifiable information will be in this consent form and in a key that the Principal Investigator (Prof. Lulich) will keep in a locked file cabinet in his office. The key will be retained only in order to facilitate follow-up with you and your child for the remaining years of this study (for a total of 3 years).

BENEFITS OF TAKING PART IN THE STUDY:

There are no benefits to your child from participation that are reasonable to expect. The data collected from your child's participation in this study will lead to increased knowledge and better understanding of speech production and development in the critical kindergarten and elementary school years, and it may lead to improved technological tools for speech-language pathologists working with elementary school children who have speech disorders.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you and your child have these options:

- a. Your child may choose not to participate.
- b. Your child may choose to end your participation in the study at any time.

CONFIDENTIALITY

Efforts will be made to keep your child's personal information confidential. We cannot guarantee absolute confidentiality. Your child's personal information may be disclosed if required by law. Your child's identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, such as the Office for Human Research Protections (OHRP), and the study sponsor (the NSF) who may need to access your child's research records.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Data collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any data is shared. Since identifying information will be removed, we cannot ask for your additional consent.

PAYMENT

Each year, your child will receive payment in the amount of \$50 for participating the MRI Session.

If only one Speech Session is required, your child will receive payment in the amount of \$100 for participating in the Speech Session.

If two Speech Sessions are required, your child will receive payment in the amount of \$50 for each Speech Session, for a total of \$100.

If three Speech Sessions are required, your child will receive payment in the amount of \$50 for the first session, and \$25 for the second and third sessions, for a total of \$100.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact the researcher, Professor Steven Lulich at (812) 856-2423. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (812) 856-4242 or (800) 696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office in Bloomington at (812) 856-4242.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You and your child may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which your child are entitled. Your decision whether or not to participate in this study will not affect your (or your child's) current or future relations with Indiana University.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to allow my child participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to allow my child to take part in this study.

Parent/Guardian's Printed Name: _____

Parent/Guardian's Signature: _____ **Date:** _____
(must be dated by the

parent/guardian)

Name of Child: _____

Child's Signature (optional): _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ **Date:** _____

**NOTE: Printed name lines are optional.