

Speech Processing in Stuttering

NCT04929184

07/11/2025

CONSENT TO BE PART OF A RESEARCH STUDY

PART 1 OF 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study title: Speech Processing in Stuttering

Company or agency sponsoring the study: National Institute on Deafness and Other Communication Disorders

1. KEY INFORMATION ABOUT THIS STUDY

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand stuttering, specifically how people who stutter may process or produce speech and nonspeech rhythms. We will do this by asking participants to perform a variety of computer or speech-based rhythm tests.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include fatigue or boredom during testing, but will generally not be more than the risks associated with daily life.

This study may not offer any benefit to you now but may benefit others in the future by increasing our understanding of stuttering. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be between 4 and 6 hours, and may occur on more than one visit.

You can decide not to be in this study. Alternatives to joining this study include not joining the study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The proposed study will help us to understand how people who do and do not stutter process speech and non-speech sounds. Information learned from the present study may help us to develop new treatments for people who stutter.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Four groups of people can participate in this study

- 1) Adults who do not stutter must
 - a. Be between the ages of 18-65
 - b. Speak English as their primary language
 - c. Have normal speech, language, hearing, and cognition
- 2) Adults who stutter must meet all of the above criteria and
 - a. Currently stutter
 - b. Score at least 10 (very mild) on the Stuttering Severity Instrument (SSI-4)
 - c. Not have attended speech therapy within the last year
- 3) Children who do not stutter must
 - a. Be between the ages of 6-17
 - b. Speak English as their primary language
 - c. Have normal speech, language, hearing, and cognition
- 4) Children who stutter must meet the above criteria and
 - a. Currently stutter and has stuttered for at least 6 months
 - b. Score at least 6 (very mild) on the Stuttering Severity Instrument (SSI-4)
 - c. Provide information regarding any current or recent speech therapy

Additionally, participants will be excluded from participation if any of the following apply:

1. Diagnosed with/undergoing treatment for any neurological, developmental, or psychiatric conditions
2. Head trauma with loss of consciousness
3. Major medical illness
4. Hearing loss
5. Moderate or severe language/motor delay (below -2SD on standardized assessments)
6. Face, motor or reflex abnormalities

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

3.2 How many people are expected to take part in this study?

This is a multisite study, meaning that it will be conducted at multiple sites in the US. We hope to enroll up to 250 adults and 100 children, across both stuttering and nonstuttering (control) groups.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to participate in this study, you will first answer some questions about your medical history (e.g., developmental milestones, speech and language, hearing, stuttering history if applicable, etc.). You will then complete some standardized tests of speech and language. You will also have a hearing screening. If you stutter, you will also provide a speech sample so that we may characterize your stuttering. This will involve a short conversation with the researcher and reading a short passage aloud. This will be videotaped so that we can transcribe your speech later. This portion of the study should take between 1-3 hours. This portion may occur over a secure video software (e.g., Zoom) depending on restrictions on in-person research activities.

Then you will complete several speech and non-speech rhythm tasks on a computer or an iPad. During these tasks you will wear a microphone clipped to your shirt so that we can record your speech into the computer. You will also wear headphones so that you can hear the stimuli. Some of these tasks can be completed remotely if required due to restrictions on in-person research. This portion of the study will take between 1-2 hours.

The study tasks described thus far can be completed all in one visit or split into two visits. Either way, you may be asked to return for one additional visit to repeat some of the speech and non-speech rhythms tasks again, lasting about 1-2 hours.

See Part 2 *Site Information* for details about any special procedures at your site.

4.2 How much of my time will be needed to take part in this study?

This study will take between 2-8 hours of your time and can be spread over several visits. Each visit should take between 1-2 hours.

4.3 When will my participation in the study be over?

Your participation in this study will be over when you have completed all of the tasks described above, or when you decide you no longer want to participate and withdraw from the study.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the Sponsor listed above.

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Other than discomfort, fatigue, or boredom associated with the research tasks, the other possible risk of participating in this study is a breach of confidentiality.

The researchers will try to minimize these risks by offering you breaks throughout the visit(s) and by protecting your private information.

See Section 9 for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in the Part 2 *Site Information* section about any injuries, side effects, or other problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. We hope to learn more about the relationship between rhythm processing and stuttering, which may eventually lead to improved treatment for stuttering.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You do not have to participate in this study and may choose not to, at any time before or after you have begun any study procedures. This study is completely voluntary and you may stop participating at any time with no penalty to you.

7. ENDING THE STUDY

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the study team persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there is no known or expect harm that could result from leaving the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

See Part 2 *Site Information*.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens 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, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the Sponsor which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Unique identification numbers will be assigned to all participants who complete the initial screening session. Only individuals working on the actual data collection with the need to have access will be able to see the identifiers. Resulting test scores, performance during experimental testing, and other data associated with each participant will be stored in a secure online research database (REDCap) or in locked cabinets in the PI and Co-I's offices. Once data has been coded, organized, and statistically analyzed, it will be stored in a computer housed in the PI's lab in

data files containing only participants' coded numbers. Consent forms will be stored separately from data in REDCap or locked cabinets. The identifiers will be maintained as long as data collection activities are ongoing, and up to 5 years following publication. Reporting of the research will involve aggregate data which will not permit identification of any individual patients.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

END OF PART 1 GENERAL INFORMATION

SEE PART 2 SITE INFORMATION FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING