

## **Speech Amplification Devices for Parkinson Disease: Talker- and Technology-Driven Enhancements**

**NCT ID:** Not yet assigned

**Date of document:** April 3, 2026 (most recent approved date)

## Research Participant Information and Consent Form

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have concerning this project.

**Study Title:** Speech Amplification Devices for Parkinson disease: Talker- and Technology-Driven Enhancements

**Researcher and Title:** Dr. Thea Knowles, Assistant Professor

**Department and Institution:** Department of Communicative Sciences & Disorders at Michigan State University

**Address and Contact Information:** Room CAS 5, 404 Wilson Road, East Lansing MI 48823

**Sponsor:** Michigan State University

**Researcher and Title:** Dr. Alice Silbergleit, Director, Speech-Language Pathologist

**Department and Institution:** Department of Neurology, Henry Ford Health

**Address and Contact Information:** 6777 W Maple Rd, West Bloomfield, MI 48322

**Sponsor:** Henry Ford Health

**Researcher and Title:** Dr. Ramya Konnai, Senior Staff Speech-Language Pathologist

**Department and Institution:** Department of Neurology, Henry Ford Health

**Address and Contact Information:** 6777 W Maple Rd, West Bloomfield, MI 48322

**Sponsor:** Henry Ford Health

### **BRIEF SUMMARY (*This is a general informed consent requirement*)**

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study of how speech amplification devices and speaking styles may affect communication in individuals with Parkinson disease and atypical parkinsonism (PD) who have noticed changes in their speech. Your participation in this study will take about 3 hours in total over two visits. You will be asked to complete questionnaires and speech tasks, including a short communicative game with another person. In some cases you may be asked to change the way you are speaking and/or wear a speech amplification device.

There are no more than every day risks associated with participating in this study. We will provide water and breaks as needed during the speech tasks.

You will not directly benefit from your participation in this study. However, your participation in this study may contribute to the understanding of communication challenges in Parkinson disease.

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar research areas to this study. However, research could also be about unrelated or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. There are plans to submit data to an archive where it will be available for future research studies. Your name and identifying information will be removed from any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data.

## **1. PURPOSE OF RESEARCH**

You are being asked to participate in this study to help researchers gain a better understanding of how to improve communication challenges in people with Parkinson disease or related conditions who experience speech changes. Our aim is to identify ways to improve communication through speech strategies and amplification devices. Your participation can contribute to research benefiting those with Parkinson disease. In this study, you will be visiting the research laboratory two times. You will be asked to complete a series of questionnaires and speech tasks. This study is voluntary.

## **2. ELIGIBILITY CRITERIA**

You will be included in the study if you:

- Have been diagnosed with Parkinson disease or related parkinsonian condition (ex: MSA, PSP).
- Have noticed changes in your speech/voice.
- Are at least 50 years old.
- Are a native speaker of North American English.

## **3. ALTERNATIVE OPTIONS**

There are no alternative procedures, but you have the option not to participate in this research study.

## **4. WHAT YOU WILL BE ASKED TO DO**

We expect that full participation in the study will take 3 hours (1.5 hours for each visit approximately). During your first visit, after a brief introduction to the study, you will be asked to participate in completing a series of questionnaires and tasks.

During your **first visit**, you will be asked to provide consent and we will conduct a series of screening measures and questionnaires. You will also be asked to talk while we record your speech.

During your **second visit**, you will be asked to complete a brief set of questionnaires, read aloud sentences, and play a brief communication game with another person. You will sometimes be asked to change the way you speak and/or use an amplification device. In a set of speech games, and you will use amplification devices in certain conditions.

We will provide breaks and water throughout the visits.

## **5. POTENTIAL BENEFITS**

While the program in which you are being asked to participate may have no immediate benefit for you, your participation can contribute to research benefiting those with Parkinson disease and related conditions. We will provide general information about your individual performance on our clinical screening measures (hearing, depression, cognition).

## **6. POTENTIAL RISKS**

There is minimal risk involved in this research program and the procedures should cause you no undue discomfort. You are not exposed to risks greater than everyday risks. If you consent to allow us to use your audio recordings as part of a future research database, there is a risk that someone who is very familiar with your voice may recognize you despite our efforts to make the recording anonymous. We will not ever record you talking about personal, identifiable information. Once the recordings are released to the database we will not be able to retrieve them because they will be stripped of all identifying information. If you are concerned about this you may choose not to have your speech recordings included in the database.

## **7. PRIVACY AND CONFIDENTIALITY**

The data recorded for this study will be collected confidentially. Information we collected from you for recruitment purposes (e.g., your name and contact information) will be stored on a password-protected electronic spreadsheet on the PI's university OneDrive account. Your name and contact information will be linked to your data through a unique participant identifier. No one outside of the study team will have access to your personal information. All information will be kept for at least three years after the close of the study. Only trained researchers under the jurisdiction of this project and the Human Research Protection Program will have access to the data collected in the study. Information about you will be kept confidential to the maximum extent allowable by law. Although we will make every effort to keep your data confidential there are certain times, such as a court order, where we may have to disclose your data. Identifying information will not be attached to any of your individual

responses or recordings when reporting results from the surveys. You will not be asked to give your name or any other information during the recording that will allow you or your place of employment to be identified. All results will be kept in a secure location accessible only to those involved in the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The results of this study may be published or presented at professional meetings, to a database, or made available to the public via the Open Science Framework but the identities of all research participants will remain anonymous. If you consent to allow us to use your audio recordings as part of a future research database, the audio recordings and derived data will be made available online. However, no identifying information will be linked to you, and nothing we will record will contain identifiable information.

Henry Ford Health's Institutional Review Board (IRB), Research Administration and Michigan State University individuals with oversight of research may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## **8. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW**

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to say no. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time. Whether you choose to participate or not will have no effect on your grade or evaluation.

## **9. COSTS AND COMPENSATION FOR BEING IN THE STUDY**

As an incentive to participate, subjects who participate in this research will be offered \$20 cash for each Visit (\$40 in total). Payment will be disbursed to participants upon completion of each visit.

There will be no charge to you for your participation in this study. The study-related procedures will be provided at no charge. You will still be responsible for the cost of your usual ongoing medical care, including procedures and drugs that are not required by this study. You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff. The sponsor and/or Henry Ford Health System will pay for the tests and examinations that are required by this study and anything else that is not part of your standard medical care.

While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care, you may be responsible for the cost of the medical care related to your condition including but not limited to laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization, and procedures.

## **10. THE RIGHT TO GET HELP IF INJURED**

If you are injured as the result of your participation in this research study and it is an emergency, please go to the nearest emergency room. There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

If you have insurance for medical care, your insurance may be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, may be billed to you. Michigan State University's and Henry Ford Health's policies do not provide financial compensation for damages, including lost wages, disability, pain or discomfort, unless required by law to do so. By signing this consent form, you do not give up any of your legal rights in the event of an injury.

## 11. CONTACT INFORMATION

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail [irb@msu.edu](mailto:irb@msu.edu) or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

You may also contact the Henry Ford Health IRB Administration Office by phone at (313) 874-4464 or by email at [irbquestions@hfhs.org](mailto:irbquestions@hfhs.org).

If you have any additional questions about the study procedures, or to report an injury, you may also contact:

- Principal Investigator, Dr. Thea Knowles (Michigan State University)
  - By phone at 517-353-6401
  - By email at [thea@msu.edu](mailto:thea@msu.edu)
  - Lab is located at Michigan State University, CAS5, East Lansing, MI 48823
- Co-Investigator, Dr. Alice Silbergleit (Henry Ford Health)
  - By phone at 248-661-7241
  - By email at [asilber1@hfhs.org](mailto:asilber1@hfhs.org)
- Co-Investigator, Dr. Ramya Konnai (Henry Ford Health)
  - By phone at 248-661-7241
  - By email at [rkonnai1@hfhs.org](mailto:rkonnai1@hfhs.org)

## 12. DOCUMENTATION OF INFORMED CONSENT

At times, it is useful to use recordings in teaching, presenting research, or future analysis. Therefore, we would like to ask for special permission to use your recordings in those contexts. Your identification would not be associated with the recording. If you do not give permission, it will not affect your ability to participate in the research.

Please mark below if you allow us to use your recordings: (1) to be presented, usually as an example in scientific reports or presentations; and/or (2) to allow your recordings to be part of a larger dataset that researchers outside of the research team could access (e.g. public recording repository). In both cases, the recordings would be anonymous.

(1) I agree to allow my anonymous voice recordings to be presented in reports and presentations for teaching purposes.

☐ Yes

☐ No

Initials \_\_\_\_\_

(2) I agree to allow my anonymous voice recordings to be part of a larger, public online dataset for other researchers to use.

☐ Yes

☐ No

Initials \_\_\_\_\_

Your signature below means that you voluntarily agree to participate in this research study.

_____	_____	_____
Signature of Participant	Date	Time

_____	_____	_____
Printed Name of Participant	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

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Printed Name of Person Obtaining Consent

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Date

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Time

You will be given a copy of this form to keep.

## **AUTHORIZED USE OF PROTECTED HEALTH INFORMATION**

A federal regulation, known as the Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission

(authorization) is required for the use and sharing of any PHI collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The Principal Investigator (PI) and the research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and the research team to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

We will collect and use:

- Name
- Phone number
- Email address
- Address
- Health history information
- Audio recordings

This health information may contain your name, address, phone number, email address, dates, medical record number, unique characteristics or code, etc.

We may release this information to the following people

- The Principal Investigator and her associates who work on or oversee the research activities.
- Henry Ford Health Institutional Review Boards (IRB)
- Government agencies and officials who oversee research (e.g., FDA, OHRP, OCR, etc.).
- The research sponsor, NIH NIDCD, and the companies they work with
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Michigan State University Human Research Protection Program

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by federal privacy (i.e., HIPAA) regulations.

This Authorization, any test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at the research study information that is not in your medical record. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This Authorization to use and release your personal protected health information does not expire. You do not have to sign this Authorization and may cancel it at any time. If you decide to cancel your Authorization at later date, you will not be able to continue to participate in this study. If you withdraw your permissions, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the following:

**Principal Investigator's Name:** Dr. Alice Silbergleit, CCC-SLP, PhD, Director, Speech-Language Pathologist

**Principal Investigator's Address:** Henry Ford Health, 6777 W Maple Rd, West Bloomfield, MI 48322

By signing this document, you are authorizing the PI to use and disclose PHI collected about you for the research purposes as described above.

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_____ Signature of Participant	_____ Date	_____ Time
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Printed Name of Participant