

Bridge2AI eConsent - Main ICF (USF) - English

Please complete the form below.

Thank you!



Informed Consent to Participate in Research Involving Minimal Risk and Authorization to Collect, Use and Share Your Health Information

Information to Consider Before Taking Part in this Research Study

Title: Bridge2AI Voice Data Acquisition

Study # 004890

Overview: You are being asked to take part in a research study. The information in this document should help you decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is led by Yael Bensoussan MD who is a laryngologist at University of South Florida. This person is called the Principal Investigator (PI). Other than that approved study staff may act on behalf of the PI.

Study Details: This study is conducted at University of South Florida (USF), Weil Cornell Medicine (WCM), Massachusetts Institute of Technology (MIT), University of Toronto (UofT), Vanderbilt University Medical Center (VUMC), Mount Sinai Hospital (MSH), Hospitals for Sick Children (HSC), Boston Children (BC), Massachusetts Eye and Ear (MEEI), Emory University, and is supported/sponsored by The National Institute of Health (NIH).

The human voice is unique to each individual and contains audio features that have been linked to diseases such as Parkinson's, dementia, mood disorders, and certain cancers. Given the advances in artificial intelligence, there is increased interest in using voice in the diagnosis of disease. Although early results are promising, many limitations remain including limited size of databases available of questionable quality and diversity. The purpose of this study is to build a large, open-source database of human voices, speech and respiratory sounds across multiple institutions with an effort to maintain high ethical standards, ensure representation of a diverse population, and include other health data to fuel artificial intelligence research related to voice.

Voice, speech and respiratory sound data will be recorded using audio recordings. Data collected will include voice tasks such as vowel sounds, free speech, oral text reading, snoring, coughing and breathing sounds. Demographic data will be collected through a smartphone application including age, sex, gender, race, ethnicity, and language. Different type of imaging may be collected from your medical record including chest x-rays, brain CT scans and brain MRIs. No imaging will be performed in the context of this study and only previously completed imaging will be reviewed and collected from your chart. You may also be asked to answer surveys and/or validated questionnaires related to your diagnosis.

You will be offered to enroll with the option to contribute with single time point data (data collected at a single visit) or longitudinal data (data collected over multiple visits).

- For single time point data collection, voice data collection will be performed in clinic during your regular office visit where you will be offered to enroll in the study and escorted to a study room after your regular appointment. The consent and data collection will be performed on the same day with a research assistant. The whole process will take 30 to 60 minutes depending on vocal tasks. If you wish or request to come back or have a separate appointment for recording data we can accommodate this request, but it is not necessary.
- For longitudinal data collection, data will be collected in 2 forms:
 - 1: Longitudinal data in clinic during clinic visits:

- This data collection will happen in clinic during your REGULAR follow up visits. No additional visits outside of your regular follow up visits are required. The maximum follow-up time will not exceed the study period of 4 years.
- 2: Longitudinal data “at home”:
 - In between clinic visits, you may be asked to perform voice data collection at home through an application that will be downloaded to your personal smartphone with the help of our research assistant in the clinic. Depending on your disease, this data collection will be at an interval of 1-6 months and for a maximum of 4 years total duration. You can decide to leave the study at any point during that time.

Subjects: You are being asked to take part in this study because you have been diagnosed with a voice disorder/ neurological disorder/ respiratory disorder/ mood and anxiety disorder that is within the scope of interest of the study.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no financial cost to participate. You will not be compensated for your participation. While there are no direct benefits to participating, we expect that the results of our study will contribute to improving disease detection through voice, with positive outcomes for public health and health research.

This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life. However, it is important to note the unlikely but possible risk of your personal information being mistakenly released and used for unconsented purposes, including to re-identify you. Privacy risks to the participants will be minimized by strict adherence to confidentiality rules. Although de-identified, there is a possible, although unlikely, risk of re-identification using voice recordings, since voice is unique to each individual. The study team will perform the study according to good clinical practices, and only the PI and the study team will have access to your medical records, REDCap records, and identifiable clinical information.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Your personal information will be kept confidential. Publications resulting from the study will not contain any identifiable information. Anyone with the authority to look at your information must keep them confidential. The confidentiality of personal information collected will be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

Your voice recording and associated voice data will be stripped of all identifiable information (such as name, email, address etc.) to protect your privacy before being uploaded to a secure database, but it is important to understand that each person's voice is unique to them. In that sense, it is possible, even if unlikely, that someone could recognize your voice through the voice recording provided.

Only authorized study team members with access to your electronic medical record will be able to access your personal information. This access is limited to what is necessary for the recruitment, follow-up and

conduction of the study. The study data containing your personal information will be uploaded to a secure, password protected network Redcap, which is behind the HIPAA firewall. In case of data transfers, agreements will be approved and signed by each institution collecting, hosting or sharing data, maintaining the confidentiality of your data.

Why are you being asked to take part?

You are being asked to take part in this study because you have been diagnosed with a voice disorder/ neurological disorder/ respiratory disorder/ mood and anxiety disorder with known effects on voice and speech. The PI and study team are trying to see whether voice has biomarkers for your particular disease category that could be screened and differentiated through AI machine learning algorithms by building a large, ethically sourced, and diverse database of related voice recordings.

Study Procedures

To determine your eligibility for participation in this study, authorized clinicians will review your medical record to screen for inclusion and exclusion criteria. Once you've been deemed eligible, we will collect the following information from your health record: demographic data including age, sex, gender, race, ethnicity, and language; clinical data related to your diagnosis including disease type, severity, and symptoms; and imaging data including chest x-ray for the respiratory disease group and brain MRI and CT scans for the neurology group. Please note that no imaging will be performed in the context of this study. Only previously completed imaging will be reviewed and collected.

If eligible, you will be offered to enroll in the study and escorted to a study room after your regular appointment. The consent and collection of voice, speech, and respiratory sound data will be performed on the same day with the research assistant. The whole process will take from 30 to 60 minutes depending on the vocal tasks linked to your disease category.

You will be offered to enroll with the option to contribute single time point data (data collected at a single visit only) or longitudinal data (data collected several times over a period time). Single time point data collection will be performed in clinic during the participants regular office visit. Longitudinal data may be collected in 2 ways: during your regular clinic visits and/or "at home" through a smartphone application downloaded to your personal device in clinic. Depending on the disease cohort, your data may be collected at intervals of 1 to 6 months and for a maximum of 4 years total duration. You can decide to leave the study at any point during that time. If you wish to schedule a separate appointment for collecting data (outside your regular clinic visit), we can accommodate this request, but it is not necessary.

Audio recording will be used for this study. You will be informed of recording and given the option to agree to the recording. While an audio recording is obtained, you may be asked to perform the following:

- Describe images out-loud
- Read passages
- Say vowels and other voice tasks
- Provide voluntary cough and breathing sounds

Total Number of Subjects

About 5 000 individuals will take part in this study at USF. A total of 30 000 individuals will participate in the study at all sites.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. If participants are students or employees, decision to participate or not to participate will not affect your student status (course grade) or job status.

The purpose of the project is not to analyze the data studied, but to build an open-source database for future research. The voice recording and associated data will be stripped of identifiable information before they are uploaded to a secure database. If participants withdraw from the study after they complete the voice data collection, their voice recording cannot be removed from the database. If participants withdraw during or before the voice data collection, their data will not be included in the database. For longitudinal data collection, participants can decide to withdraw from the longitudinal data collection at any point. In that case, only the data collected prior to their withdrawal will be kept in the database. The minimal requirement for participation is 1 data collection time-point.

Benefits

There are no direct benefits to participating in the study. However, we expect that the results of our study will contribute to improving disease detection through voice, with positive outcomes for public health and health research.

Risks or Discomfort

Participation in this study involves the collection of: your voice, speech, and respiratory sound recordings; demographic, clinical, and imaging data from your existing medical record; and survey/questionnaire responses. Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer. If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of this study as soon as possible.

Voice collection is a safe non-invasive collection method with minimal physical and psychological risk. Privacy risks associated with this study include the risk of your personal information being mistakenly

released and/or used for unconsented purposes, including to re-identify you. The confidentiality of your personal information will be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s). Risks to the participants will be minimized by strict adherence to confidentiality rules. In addition, the study team will perform the study according to good clinical practices, and only the PI and the study team will have access to your personal information.

- We take great care to protect your information and identity. Personal data that can be used to directly identify you will be separated from the research data (voice recordings and de-identified survey answers) during collection itself to remove as much risk as possible of re-identification. However please note, that there is always a low risk that someone may attempt to re-identify an individual by referencing other sources of information (e.g., your social media).
- Voice is unique to each individual. Although we will ensure no identifiable information is linked to your voice recording, there is still a minimal risk of re-identifying you using your recording. Additionally, voice changes with age, speaking style (for example scripted or spontaneous), and with different emotions. This means that in a few years, your voice may no longer be a 100% match to the recordings collected for this study which would further prevent your identification.
- Accidental public disclosure may occur due to unintended data breaches including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.
- Data collected in this study may count against your existing data plan if you participate on a mobile phone or tablet with access to data. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan.

Participation in this study may involve additional risks that are not known at this time. For example, more advanced technologies capable of identifying you based on your voice recordings could be created in the future. You will be told about any new information that might change your decision to be in this study.

Compensation

You will receive no payment or other compensation for taking part in this study.

Costs

It will not cost you anything to take part in the study.

Privacy and Confidentiality

Per USF policy, your voice recording will be kept for 5 years after the completion of this study. However, we will plan to keep your voice recording (stripped of any identifiable information) for at least 50 years in an open-source database, which means it will be made accessible to researchers worldwide to advance knowledge in the field of disease detection using voice. Although we cannot predict the specific uses that will be made of your data, we ensure that the database will only be accessible to private or public research projects which have received an IRB approval.

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may

need to see your study records. These individuals include:

- The study team, including the PI, collaborating researchers at USF and other universities, study coordinators, study nurses, and all other study staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this study. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.
- The sponsor for this study which is the National Institutes of Health (NIH)

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative.

Voice recordings and voice data included in the database will not contain any identifiable information. Your de-identified information or recordings could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

If completing an online survey or app-based audio recording, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a subject in the research project under certain circumstances. The investigative team will voluntarily comply with Florida Statutes and federal regulations, which may mandate or permit certain disclosures of protected information by the investigative team to appropriate individuals.

What if new information becomes available about the study?

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

The purpose of this study is to collect human voice data in order to build a large database to fuel future voice research using artificial intelligence. This study only requires collection of data and will not involve analysis of the data collected. Therefore, no clinically relevant findings will be attained or reported to you during the course of this study. If you believe you are having symptoms that may require care, you should contact your primary care physician.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Yael Bensoussan, M.D. At (323) 509-6483. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your de-identified health information and may use that information to conduct this research:

- The medical staff that takes care of you as a participant of this study and those who are part of this research study;
- Each research site for this study including: University of South Florida (USF), Weil Cornell Medicine (WCM), Massachusetts Institute of Technology (MIT), University of Toronto (UofT), Vanderbilt University Medical Center (VUMC), Mount Sinai Hospital (MSH), Hospitals for Sick

Children (HSC), Boston Children (BC), Massachusetts Eye and Ear (MEEI), Emory University, and Cleveland Clinic

- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;
- All designated review committees such as the IRB at each collaborating institution
- Data Safety Monitoring Boards or others who monitor the data and safety of the study

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDS, mental health, substance abuse, and/or genetic information.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a subject in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and staff may need to follow-up with you if there is a medical reason to do so

To revoke your authorization, please write to:

Principal Investigator
For IRB Study # 004890

Department of Otolaryngology--Head & Neck Surgery
University of South Florida
12901 Bruce B Downs Blvd

Tampa, FL 33612

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me. I understand that by filling out the best future contact below, I am consenting to be contacted in the future for further voice data collection if long term follow up is required as part of an eventual extension of this grant after the 4-year duration. Please select one of the three statements below that you consent to.

- I consent to having all data I submit shared only with the researchers of this study.
- I consent to having all data I submit shared with the researchers of this study and to having my audio recordings and de-identified written responses shared with other qualified researchers.
- I consent to having all data I submit shared with the researchers of this study and to having my audio recordings and de-identified written responses shared with other qualified researchers as well as publicly in the form of an open-source database.

Signature of Person Taking Part in Study
[Authorization]

Date

Printed Name of Person Taking Part in Study

Best form of contact for future voice data collection
(leave blank if you do not want to be contacted)

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what they can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Social-Behavioral Adult
2023

Version #1

Version Date: January 16th,

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Signature of Person Taking Part in Study
[Authorization]

Printed Name of Person Taking Part in Study

Date
