University of Arkansas for Medical Sciences Informed Consent Form with Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- **When we say "I" or "me," (or "you" and "your") we are talking about the person who takes part in the research and the person who gives the permission to be in the research.**
- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from University of Arkansas for Medical Sciences (UAMS) even if you are not in the study.**

Research Authorization

Why am I being asked to be in this research study?

- We want to learn more about how to help people who have a brain condition that will likely get worse over time, like Parkinson's disease. We want to see if changes in smell, voice, and the cells inside the nose can help predict these brain disorders in some people. To do this, we want to compare these things in people with these brain conditions to people who have problems related to their voice, but don't have a brain condition.
- You are being asked to join this research study because you either have Parkinson's or another degenerative brain disease, or are otherwise healthy with voice tremor or other changes in the voice box and are scheduled to have a voice evaluation bu an ENT doctor at UAMS. We plan to include up to 60 people ages 18 to 90 in this study:
- Being part of this study is voluntary. This means you can decide to say yes or no to being part of this study. Neither decision will affect your present or future medical care at University of Arkansas for Medical Sciences.
- This informed consent may contain words you do not understand. You are free to ask as many questions as you like before you decide whether you want to join this research study. You can ask questions at any time before, during, or after your participation in this research. You will not incur a penalty or loss of benefits if you refuse to participate or withdraw early from the study.

- If you agree to take part in this study, you must sign this consent form. A signed copy of the consent form will be given to you. You are not waiving any legal right by signing this consent form.

What if I say yes, I want to be in this study?

- If you say yes, we will:
  - ✓ Have you sign this informed consent form
  - ✓ The study will involve two separate visits, which may happen on the same day or on separate days based on what works best for you and the investigators
  - ✓ For one of these visits, we will have you come to the Translational Research Institute (TRI) on the 5th floor of the Jackson T. Stephens Spine Institute, where we will:
    - Record your demographic information (age, sex, race, ethnicity)
    - Record a complete medical history, including the medical history of your 1st and 2nd degree family relations (for example grandparents, parents, brothers or sisters, children, grandchildren) to the best of your knowledge
    - Ask you to provide a list of all medications you may be currently taking including all prescription, over the counter (OTC), and alternative medications, supplements and therapies. You should also tell us about any additions, deletions or changes in the doses of these medications in the last 6 months
    - Do a complete neurologic examination, including vital signs (body temperature, heart rate, respiration rate, blood pressure)
    - Test your ability to think (cognition) using questionnaires and a camera system that tracks your eyes while reading a paragraph of text on a computer screen.
    - Have you complete questionnaires designed to see if you are depressed, anxious, your quality of life including vision related quality of life, or difficulty with walking , or
    - Evaluate your ability to perform activities of daily living
    - Give you a Smell Test to check your smell sensation. To do this test, you will be asked to use booklets that contain scratch and sniff patches. You will sniff each patch with one nostril and then choose which response best describes each patch. You will take the test by yourself, although the study staff will guide you in taking the test. It usually takes about 10 to 15 minutes to take this test. Some people will be asked to take the test at the beginning and then

at the end of their physical and neurological exam, and instructed to use one and then the other nostril while closing the opposite nostril with their finger when inhaling or sniffing the smell while taking the test. This helps us see if there are differences in smell identification between the left and right nostrils.

- Your neurology clinic visit will take about 2 hours.
- If there are any concerns for neurodegenerative disorders based on these examinations (for example for the group with voice tremor or presbylarynx where a degenerative disorder was not suspected before the exam), the neurologist completing the examination will discuss this with you and may provide a referral for clinical assessment.

✓ For the other visit, when you come for your clinically scheduled evaluation of the voice-box to the UAMS ENT Clinic on the 3rd floor of the Jackson T. Stephens Spine and Neurosciences Institute, we will:

- Take a, Oral and Nasal Swab: Your doctor will take samples from the lining of your mouth and nose using a swab. For the nose swab, we will first numb the inside of the nose with an anesthetic. A tiny camera will be placed into the nose so we can see the nose's lining. We will then collect cells on a swab from inside your nose 3 or 4 times. The lining of the nose will be inspected for any signs of injury. For oral swabs, we will firmly scrape the inside of the cheek with a swab.
- Give you your scheduled Laryngeal Evaluation: Once nasal swabs have been obtained, the tiny camera will be advanced through the passage of the nose to the top of the throat. This is to allow the ENT doctor to see the larynx (voice box) and pharynx and hypopharynx (throat) structure and function. A built-in light will allow the doctor to see the voice box activation when you produce sound. This test is commonly done in ENT clinics. Although the evaluation itself is no different from what you were scheduled to undergo for the clinical work-up of the underlying problems with the throat and voice-box, the recordings of the laryngeal evaluation will be used for research purposes.
- The visit in the ENT clinic is expected to take one and a half hours.

Table 1. Your Study Schedule

Activity	**Neurologist visit**	**ENT and Speech therapist visit**
Study eligibility and consents (Can happen either during Neurologist or ENT visit)[2]	X	X

Demographic Information[1]	X	X
Vital Signs[1]		X
Medication Profile[1]		X
Complete Neurological Examination[2]	X	
Complete Movement Disorders Examination[2]	X	
Smell evaluation using the UPSIT test[2]	X	
Parkinson's disease rating scales[2]	X	
Cognitive test [2]	X	
Nasal swab[2]		X
Laryngeal evaluation with a camera passed through the nose to the throat[1]		X
Voice evaluations by speech therapist[1]		X
Review of brain scans and Neuropsychological Evaluation (if available)[2]	X	

[1] Routine clinical assessments
[2] Research-related assessments

See the table above for the study procedure schedule. There will be two separate study visit. Which one you do first depends on whether you have a brain disease or not. If you have a brain disease, the neurology clinic tests will be done first. If you have a voice problem, you will have the ENT clinic visit first. The second visit for both groups will be set up after the first visit. .

What if I don't understand something?

- This form may have words you don't understand.
- You can ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you are in the study.

How long will this study take?

- Your participation in the study will last two visits (approximately 2 hours each), which may be spread over up to a year from you giving your permission to participate. You

may stop your participating at any time. The total length of the study will be until all 60 subjects are evaluated.

What if I say no, I do not want to be in the study?

- Nothing bad will happen.
- You can still get your medical care at UAMS.

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time and have your data and samples withdrawn by calling Dr. Rohit Dhall, MD at (602) 503-3193 or Dr. Ozlem Tulunay Ugur, MD at (501) 686-5878. We may still use and share your information that was collected before you request your removal from the study.
- If you change your mind about being in the study during one of the study visits, just let the study team know and we will stop the study tests.
- You can still get your medical care at UAMS if you decide to drop out of the study early.

Can I be taken out of the study even if I want to continue?

- Yes, the study doctor can take you out of the study if:
  - ✓ You do not follow study instructions.
  - ✓ It is not in your best interest to continue.
  - ✓ The study is stopped for any reason.

Are there any alternatives to being in this study?

The only alternative is to not be in the study.

Who will see the information about me that is collected? How will my personal information be used and protected?

- The only people allowed to see your information are the people who work on the study and people who make sure our study is run the right way. They are:
  - ✓ UAMS IRB (Institutional Review Board)
  - ✓ Other institutional oversight offices
  - ✓ OHRP (Office for Human Research Protections)
  - ✓ By law, the researchers must give certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possible occurred or you disclose a desire to harm yourself or others.

- Your personal health information will be given a unique study code and will be stored:
  - Paper information – locked up in a secure office. Only the research team will have access to this data. A copy of this form will also be locked in our files. We will not put these into your medical record.
  - Electronic information – in a secure computer database. Your personal information will be coded with a unique study subject number that does not identify you. A list linking the unique number with your identity is stored separate from your study information. Only the study team will have access to this data.
  - We will keep the list linking the codes to your identifying information only as long as we have to by law. Then we will destroy the list.
  - When we share the results of the study in medical journals or presentations we will not include your name or anything else that can identify you. We will do our best to make sure no one outside the study knows you are part of the study.

- If we discover any health issues from your history and physical examination, we will let you know and recommend that you contact your primary care physicians for any follow-up that may be needed. If you do not have a primary care physician a referral could be made to a physician at UAMS if you request it. However, we will not return any results from the nose swab specimens to you, as these are research results that are not backed up by traditional testing.

Will my information be used for anything else?

- The information and samples we collect from you about you may be stored in a research laboratory at the Institute of Aging at UAMS for future research. They would be stored without anything allowing anyone to directly identify you. The samples and information may be used by us or by other researchers in future studies looking at markers for degenerative brain diseases. Other than the Apo-E genotyping that will be done as a part of initial processing of the samples, no additional genetic testing will be allowed on these samples by future researchers.

Please check the appropriate box below to tell us if we can not use your de-identified (no names) information and nose swab specimens for future studies indefinitely.

☐ DO NOT use my de-identified information or nose swabs for further studies.
☐ My de-identified information may be used, BUT NOT THE SWABS for further studies.

Will it cost me anything to be in the study?

- The study will not cost you anything. You or your insurance company will be responsible for your regular medical care as usual.

- The screening questionnaires, cognitive testing and smell testing, neurological history and examination are being done as a part of this research study and will be undertaken at no cost to you. Neither you nor your insurance company will be charged for them. Therefore, you should not claim these expenses from your insurer. The routine care portion of voice box evaluation and speech therapy assessments will be billed to you or your insurance company in the normal manner.

Will being in this study help me in any way?

- Being in the study will not help you, but may help people with Parkinson's or another degenerative brain disease in the future.

Will I be paid?

- We value your participation, but will not be paying you for taking part in this study.

What are the risks of being in this study?

- The risks are:
  - ✓ Someone could find out that you were in the study and learn something about you that you did not want others to know.
  - ✓ Irritation or soreness of the throat or nose after the nose swabs or voice box assessments

What if I get sick or hurt while I'm in this study?

- If you get hurt when you are here for the study, we will help you get the care you need.
- If you get hurt or sick when you are not here, you should call your doctor or call 911 in an emergency. If your sickness could be related to the research study, tell the doctor or ER staff about the study, the name of the head of the study and give them a copy of the consent form if you have it. Call the head of the study Dr. Rohit Dhall at (602) 503-3193 or Dr. Ozlem Tulunay-Ugur at (501) 686-5878as soon as you can.
- Costs for your care will be billed to you or your insurance company. Some insurance companies, Medicare, and Medicaid may not pay your bills that are related to research.

What if I have questions?

- Please call the head of the study Dr. Rohit Dhall at (602) 503-3193 or Dr. Ozlem Tulunay-Ugur at (501) 686-5878if you:
  - ✓ Have any questions about this study.
  - ✓ Have questions about your rights.

- ✓ Feel you have been injured in any way by being in this study.

- You can also call the office that supervises research (UAMS IRB) at 501-686-5667, if you:
  - ✓ Have questions about this study.
  - ✓ Have questions about your rights.
  - ✓ Can't reach the study team.
  - ✓ Need to speak to someone not directly involved with this study.

What should I do if I want to be in the study?

- Sign this form. We will give you a copy of the form to keep.

UAMS HIPAA Research Authorization Form

What is HIPAA?

HIPAA is the Health Insurance Portability and Accountability Act of 1996. It helps to keep your health information private and secure. When we say "you" or "your", we are talking about the person who takes part in the research and the person who gives the permission to be in the research.

What is the purpose of this form?

We are asking you to take part in the research described in the consent form. To do this research, we need to collect health information that tells who you are. We may collect the following information about you:

- Age, gender, and other demographic characteristics
- Height and weight
- Your medical history, physical, neurological and speech-language exams (including tests of cognition)
- Laryngoscopy/stroboscopy
- Gaze tracking during reading
- Symptom questionnaires
- Nasal swabs and smell test results
- Information about your medical history and treatment included in your medical records.

This information will be used to study Parkinson's and other neurodegenerative disease. We will only ask for information we need for the research. Being part of this study will create the following new health information: Information that is created or collected from you during the study including physical examinations and movement disorders examinations, tests of smell, tests of voice function, voice box structure and function, and tests of your thinking, and any side affects you may experience;

To be in this study, we need your permission to collect, create and share your information.

What will happen with my health information?

If you sign this form, we may share your health information with people at the University of Arkansas for Medical Sciences (UAMS). These are people who help with the research or things related to research, such as:

- the research staff

- the office that supervises research UAMS IRB (Institutional Review Board))
- other institutional oversight offices

We may also need to share your health information with people outside of UAMS who make sure we do the research the right way, such as OHRP (Office for Human Research Protections). Some of the people outside of ACH and/or UAMS may share your health information with someone else. We cannot protect your health information once it leaves UAMS.

What happens if I sign this form?

Signing this form means you are agreeing to be in this research study. You are giving us permission to create, collect, use and share your health information as described in this form.

What if I don't sign this form?

You do not have to sign this form. If you decide not to sign this form, you cannot be in the research study.

If you decide not to sign this form, this will not affect your current or future medical care or benefits at UAMS.

What if I sign this form but change my mind later?

You can change your mind at any time. This will not affect your current or future medical care or benefits at UAMS. If you want to leave this study, follow these steps:

- write a letter saying you have changed your mind and that you are "revoking your HIPAA Research Authorization"
- list the "Study Title" listed on this form in your letter
- sign the letter
- send the letter to Dr. Rohit Dhall, 4301 West Markham, St – Slot 500, Little Rock, AR, 72205

We may still use and share your information that was collected before you sent the letter asking to leave the study.

When does this permission expire?

The permission you give us will be in effect indefinitely, unless you tell us to stop.

By signing the document, I am saying:

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all my questions.
- I have been asked if I wish to talk directly to the research study doctor.

I know that:

- I can stop being in the study at any time and nothing bad will happen to me.
- I can call the office that supervises research (UAMS IRB) at 501-686-5667 if I have any questions about the study or about my rights.
- My decision will not change my medical care at UAMS.
- I do not give up any of my rights by signing this form.

STATEMENT OF THE SUBJECT

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I understand that my health information can be collected and used by the researchers and staff for the research study described in this form and the research consent form. I have been told that I will be given a copy of this consent/HIPAA Authorization form.

The health information about_____ can be collected and used by the researchers and staff for the research study described in this form.

(Signature of Participant or Participant's Legal Representative)	(Date)
(Relationship to Participant)	
(If Patient's Legal Representative, signature of patient assenting to study)	(Date)
(Signature of person obtaining consent)	(Date)

[Subject Medical Record]

[Sticker Goes Here]

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