UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Mechanisms of airway protection dysfunction in Parkinson's disease

3. Who do you call if you have questions about this research study?

Principal Investigator:

Karen Hegland, PhD, CCC-SLP (352) 294-8366

(352) 359-1830 (after-hours)

4. Who is paying for this research study?

The sponsor of this study is the National Institutes of Health

5. Why is this research study being done?

The purpose of this research study is to determine the reasons why people with Parkinson's disease (PD) develop problems swallowing and coughing, and how they change with disease progression. We have studied both swallowing and cough in PD for several years now, and we have identified that reduced sensation of breathing difficulty or change may be related to problems swallowing and coughing in people with PD. For this study, we will be conducting several tests of swallowing, coughing, and breathing. We will do these tests 1 time per year for 3 years.

You are being asked to be in this research study because you have Parkinson's disease, and may agree to voluntarily participate.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

No part of this research study is being completed as part of your normal clinical care. If your physician determines that you need a swallowing evaluation, the swallowing test described in number 7 can be used in place of a separate clinical test.

7. What will be done only because you are in this research study?

If you agree to participate in this research study, and sign this form, we will ask you some questions related to your health history. These questions include:

- Do you have a history of stroke, or any neurologic disease *besides* Parkinson's disease?
- Do you have a history of cancer of the head, neck, or lungs?
- Do you have a history of any breathing disorders or diseases?
- Are you allergic to capsaicin or hot peppers?

- Have you smoked in the last 5 years?
- Have you smoked in the past for longer than 5 years at a time?

We will ask these questions to make sure you do not have a history of any illnesses that would affect your ability to swallow, or cough, or that would make it unsafe for you to participate. If you do, you will not continue with the study.

If you agree to participate, we will also ask you to fill out two short questionnaires that ask about how you feel (for example, whether you are happy, sad, feel indifferent to things, have energy, etc.). If your answers indicate you may be depressed, the researcher will provide you with contact information for the UF psychiatry and psychology clinic. If your answers indicate you may be *severely* depressed, you will not continue with the study.

After completing the questionnaires, there will be several study tests that we will ask you to do. They may not be done in the exact order that they are listed in on this form. The researchers will tell you which test will be done, and give you instructions on how to do it.

Breathing tests:

We will measure your breathing using *pulmonary function testing.* This testing involves breathing forcefully and quickly several times through a mouthpiece connected to a computerized machine. This machine measures how much air you are able to move, and how quickly you are able to move air. The pulmonary function testing will require you to breathe with maximal effort. For example, the researcher will ask you to take as much air into your lungs as you can. Then you will be asked to breathe out as much of the air in your lungs as you can.

We will measure how easy or difficult it is for you to inhale while you breathe through a mouthpiece connected to some small plastic tubes that deliver different respiratory loads. Respiratory loads provide resistance to airflow, making it feel like it is more difficult to move air into your lungs. The respiratory loads can be adjusted to make it harder or easier to inhale. To begin, you will be seated comfortably in a chair. We will show you a scale numbered from 0-20. The numbers on the scale indicate how difficult you think it is to inhale. The scale ranges from 6 (not difficult at all) and 20 (maximally difficult). We will then begin breathing through a mouthpiece and let you get used to breathing on it without any respiratory load. We will also deliver some examples of the respiratory loads so you know what to expect.

Next we will begin delivering a total of 5 different respiratory loads. The loads will be delivered randomly, and will not be delivered on more than one breath in a row. Each breath with a load will be separated by several normal breaths.You will receive each load between 3 and 5 times, for a total of 15-25 loaded breaths. Following each loaded breath, we will ask you to rate on the 0-20 scale how difficult you think it is to inhale. We will do this procedure two times.

Cough tests:

We will measure your coughing using a facemask that will fit securely around your nose and mouth. This will be used to record airflow during different coughing tasks we will ask you to do. All of this equipment will be connected to a computer, which will record the data so we can measure it at a later time (after you complete the study). We will measure 2 types of cough: "reflex" and "voluntary" cough. These are both described below:

-**Reflex cough:** We will measure your reflex cough using the facemask, which will be connected to some tubes and a nebulizer, or a device that makes vapors out of liquids. We will use a type of vapor made from capsaicin ("hot pepper vapor"). There will be up to 5 different concentrations, or strengths of the vapor. Each time the vapor is delivered, you will inhale it once and then cough if you need to. After each vapor, we will ask you to rate your urge to cough using a scale of 0-10, with 0 equaling no urge to cough, and 10 equaling the greatest urge to cough. If you do not cough to any of the vapors, we will present one final stronger dose. There will be a 2 minute break in between each presentation of the vapor, and water will be available at all times throughout the study.

-Voluntary cough: We will measure your voluntary cough by asking you to cough several times in a row, as if something went down the wrong pipe. You will do this three times.

The reflex and voluntary cough tasks will be done in random order. That means that not everyone will complete them in the same order. The researchers will tell you whether you will do the voluntary or reflex cough first.

Swallowing test:

The swallowing test is performed in the radiology department. You will be seated and asked to swallow thin liquid barium, pudding barium, and pudding barium mixed with a solid. We will ask you to swallow these consistencies while a series of X-ray pictures are taken. We will provide the barium to you, then the X-ray camera will be turned on, and you will be told when to swallow. These pictures will be recorded on to a computer and later analyzed to help us understand if the hidden structures of your mouth and voice box are working effectively to produce a safe swallow. Water will be provided at the end of the test. This will take approximately 5 - 15 minutes. A swallowing evaluation does expose you to small amounts of radiation. We will do our best to limit this exposure as much as possible.

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

There will be 3 research study visits that last between 1.5 – 5 hours each. The 3 visits will be spaced approximately 1 year apart. If you also participated in our other protocol that included identical measures, those measures will be used for this study and therefore you will only complete 2 additional study visits.

9. How many people are expected to take part in this research study?

Up to 180 people are expected to participate.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The breathing measures we will make during this study can make some people feel breathless. The respiratory load tests may give you the feeling that breathing is difficult when the loads are applied. We will work to minimize these feelings by encouraging you to relax and breathe, and by allowing breaks during the tasks to breathe without the facemask.

The short tests that will ask about how you feel may make you feel sad or uncomfortable. If we determine that your answers on those tests may indicate you are depressed, we will provide you with contact information for UF psychiatry and psychology in case you would like further evaluation.

There is a chance that you may be uncomfortable with breathing the capsaicin. Capsaicin is derived from hot peppers and makes many people cough, which is a normal reaction. We have tested over 300 research subjects with capsaicin and never had any adverse events. Most people report a “tingling” or “hot” sensation that passes quickly with time and water. Water will be available to you throughout the entire study.

When swallowing liquids and foods there is always the potential that they may “go down the wrong pipe.” If this happens and causes coughing you will be given as much time as you need to cough and relieve the sensation.

This research study involves exposure to radiation from x-rays. The radiation exposure you will receive from the videofluoroscopy is about 150 millirems per test (1 test is performed per year). This radiation exposure per test is equivalent to 6 months of natural background radiation to which people in the United States receive each year.

The risk from this radiation exposure is considered to be minor when compared with other everyday risks. However, the effects of radiation add up over your lifetime. Repeated exposures may increase your risk of injury or disease. When deciding to enter this study you should consider previous and future potential exposures. Examples would include x-rays taken for a broken bone or radiation therapy treatments for cancer. The investigator will provide you with a contact person if you would like more information about radiation exposure.

Other possible risks to you may include: None that we know of at this time.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

11a. What are the potential benefits to you for taking part in this research study?

It is possible that you will not directly benefit from participating in this study.

If you have not previously received a swallowing evaluation, you may benefit from having this procedure and receiving recommendations for managing your swallowing problem.

11b. How could others possibly benefit from this study?

By learning about the factors leading to difficulty protecting your airway with swallowing and coughing, we hope to be able to improve our future evaluation and treatment options for people with PD

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Other than the swallowing test, no part of this research would be included as part of normal clinical care. Therefore, there are no alternatives to those parts of the experimental procedure.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact the study team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your permission will be sought to use information collected on you prior to your withdrawal.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in the study because you do not meet the study requirements. Ask the principal investigator if you would like more information about this.
- The investigator decides that continuing in the study would be harmful to you.
- Study materials have a bad effect on you.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Drugs

Capsaicin will be provided at no cost to you while you are participating in this study.

Study Services

The Sponsor will pay for or provide the following study-required services/activities at no cost to you:

1. Pulmonary function testing
2. Measure of how easy or difficult it is to inhale
3. Voluntary and reflex cough testing
4. Swallow test

If you receive a bill for these services, please contact Karen Hegland, PhD, CCC-SLP at (352) 294-8366.

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

You will be paid $50.00 for each study visit, for a total of up to $150.00.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or

psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

We will collect:

- Name (not used or shared with others)
- Age
- Gender
- Parkinson's disease severity information
- Pulmonary function measures

- Sensation of breathing difficulty during the occlusions
- Swallowing evaluation data
- Depression and apathy scale measures

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

The data being collected in this study will be used to determine how swallowing and cough change over time in people with PD.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date