Title: Establishing Normal Swallowing and Breathing Profiles in Healthy adults across the age span

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Establishing Normal Swallowing and Breathing Profiles in Healthy adults across the age span

Key Personnel:

Principal Investigator: Emily Plowman, PhD, CCC-SLP; (352-273-9215)

Co-Investigators: Ianessa Humbert, PhD, CCC-SLP

Other research staff: Lauren Tabor, MS, CCC-SLP (study coordinator, 443-536-1234)Raele Robison, MS; Andrea Siluk, BS; Rachel O'Neal, BS; Alycia Rivet, BS; Alessandra Gallastegei, BS, Alayna Ernster, Alicia Vose, CCC-SLP, Karen Hegland, CCCSLP, PhD, Julia Mikaela Apostol

Background and Significance

The prevalence of dysphagia may be as high as 22% in individuals over 50 years of age (Howden, 2004). There are few therapeutic options and minimal management strategies offered to treat these individuals and improve sequelae of dysphagia. Dysphagia contributes to malnutrition, aspiration, pneumonia, reduced quality of life and increased mortality in neurodegenerative disease such as ALS (Tabor et al 2016, Chen, 2005; Burkhead, 2014). One reason for this is the lack of normative data across various measures of swallowing and respiratory function. As a result, detecting early impairments in swallowing physiology is difficult, given the variability of swallowing and unknown normative value range of swallowing physiology. Therefore, the goal of this study is to complete clinical tests of swallowing and cough function in healthy volunteers to establish normative data. This will contribute to future study in disordered populations, to determine degree and severity of impairment and efficacious treatment and management strategies based on impairment.

Purpose: The purpose of this study is to establish normative values for clinical testing measures of swallow, respiratory and cough functions. This will aide in establishing degree of impairment in disordered populations, and in identifying efficacious treatment paradigms for dysphagia.

Study Setting

Swallowing Systems Core Laboratory in Shands Hospital at the University of Florida (DG 130, 136, DG 76 and DG 77).

Population and Sampling Data

Participants will include up to 120 adults, both males and females across the lifespan. The primary goal of the proposed study is to establish normative data for comparison

with disordered dysphagic populations in an age and gender matched fashion. This study represents a pilot study and the work proposed and comparisons planned have not yet been performed in the dysphagic population using clinical testing measurements. Given that some volunteers may not be able to complete all required tasks and lead to missing data we will recruit and run 20% additional then our target number of 100 for a total of 120 participants. drop and some data may not be included, we plan to study approximately 100 participants. A power analysis is not included in the protocol as we are conducting the first study to collect normative data and establish a database of 'normal' functioning across various swallow and respiratory parameters.

Inclusion/Exclusion Criteria.

A total of 120 individuals will be included in this study. Subjects will include both male and females who are aged between 18-100, healthy and with no major medical conditions. Adults who are pregnant, or those with major medical conditions (i.e., swallowing impairment, brain injury) will be excluded from this study. Anyone with allergy to barium will be excluded from this study. No specific gender or race will be excluded or targeted for participation in this study.

Recruitment Plan and Consenting Process

Potential participants will be identified through word of mouth, Health Street and advertising via approved flyers within the University of Florida campus and surrounding areas of Gainesville. We will also post approved flyers advertising participation in the study. Interested volunteers will be given an informed consent and given ample time to read over this and ask any questions and given the option to take home informational material to determine if they would like to participate. Prior to consenting, all participants will be screened to determine eligibility for the study. To determine if you are eligible for the study, who are considered to be of childbearing age (less then 60 years) will be asked to complete a pregnancy test to confirm they are not pregnant prior to performing the exam. If a person consents to be in the study, they will sign the ICF document and provided with a hard copy of the consent material. Study personnel will arrange a single, one-hour appointment time to perform the study. No costs will occur for being in this study. Each participant will receive a parking voucher, as needed, for participating in the study and a $50 compensation will be provided to each volunteer to cover any expenses associated with attendance

Protocol:

This study will involve a **single 90-minute visit**. All women under the age of 62 will be asked to complete a pregnancy test as part of the screening process during to radiation

exposure. Eligible participants will then undergo testing to determine their individualized Maximum Expiratory Pressure (MEP), maximum inspiratory pressures (MIP), voluntary and reflexive cough testing, tongue pressure testing and a comprehensive instrumental swallowing evaluation (that will include either videofluoroscopy, manometry, or simultaneous swallowing and manometry study). The entire duration of the exam will be under 90 minutes and the participant will be free to leave at any point during the examination.

Procedures:

Respiratory Testing:

The participants' maximum expiratory/inspiratory pressure (MEP/MIP) will be assessed using a hand-held digital manometer (MP01, Micro Direct Inc.). The subject will be standing and while wearing a nose clip be asked to blow out as hard and fast (MEP) or in as hard as they can (MIP). Forced vital capacity (FVC), a maximum effort breathing test assessing maximum volume exhaled, will also be completed. These tests will be completed a maximum of three times to obtain values within close range of one another. Subjects will also complete maximum effort cough testing, both voluntary and reflexive testing using a spirometry and pneumotachograph setup (Lab Chart Version 7).

Videofluoroscopy and Barium:

The swallowing systems core laboratory is fully equipped to perform videofluoroscopy with a c-arm (OEC 9900) that is dedicated solely to research purposes. Videofluoroscopy recordings will be kept to a minimum and turned on only during completion of a specific testing task. Video recording and images captured during the videofluoroscopy will be synced and saved for data analysis. Videofluoroscopy allows for time-synced, frame-by-frame data analysis for the specific measures taken during swallowing tasks. The physiological swallowing measures (temporal and kinematic movement of the base of tongue and hyolaryngeal complex during swallowing) to be analyzed cannot be visualized with any other technique. All swallowing tasks will be completed using barium in order to visualize the bolus during movement of various swallowing muscles and structures. A standardized barium protocol will be administered that will include thin liquid, nectar thick liquid, honey thick liquid, pudding and a solid cracker. We do not expect aspiration (bolus into trachea) to occur during this study given we are recruiting individuals with no prior history of disease or disorder, and aspiration is uncommon is normal swallowing individuals. Swallowing tasks during videofluoroscopy will consist of comfortable size cup sips/bites in various head positions (i.e., head turned, chin tucked down). In addition to swallowing trials , the participant may be asked to perform a list of commonly utilized swallowing therapeutic maneuvers

that will include: a chin tuck, a head turn to the left and right, a tongue press maneuverer and a breathing maneuver to allow quantification of the physiologic impact of these tasks on the upper aerodigestive tract in healthy adults. These tasks will also be utilized during the High Resolution Manometry procedure, explained below.

High Resolution Manometry:

During the manometry portion of the evaluation, we will be using a small pressure tube that gets inserted into the nose and travels down to the back part of the throat. After the tube is in place in the throat, the subject will sit comfortably for five minutes to acclimate to the tube being in this position. After this time, they will be asked to swallow several teaspoon-sizes of a saline solution. Saline is a thin-water like solution that has a slightly salty taste. They may feel a slight discomfort as the tube is being placed in position and as they begin to swallow the saline with the tube in place. Time to complete all swallowing-related tests will be approximately 30 minutes and participation in this study will require only one visit. Individuals have the option to decline this procedure if uncomfortable or difficult to tolerate.

Tongue Pressure Examination**:**

During the tongue examination, we will measure tongue strength and the maximum amount of time that the subject can apply pressure to an air-filled tongue bulb that will rest on the roof of your mouth. Lingual function will be evaluated using the Iowa Oral Pressure Instrument (IOPI). The Iowa Oral Pressure Instrument (IOPI) model 2.3 is a device that measures the peak pressure performance of lingual strength and endurance via the action of a bulb placed on the hard palate. The patient elevates the tongue to touch the roof of the mouth and pushes against the bulb. To assess maximum anterior isometric pressure, the bulb will be placed on the roof of the mouth and the participant will raise his or her tongue to apply pressure to this bulb and then quickly release the tongue back into a neutral position.

Tongue Function Testing:

We will also perform a technique called electrical impedance myography (EIM) of the tongue. EIM allows us to learn more about the health of the composition of the tongue muscle. We will gently rest a small tongue depressor containing a special sensing electrodes on the top of the tongue. We will then have the subject close their mouth for two seconds while the electrode obtains information about the composition of your tongue. They will not feel anything while the tongue depressor is resting on your tongue.

Cough

Voluntary Cough Testing:

Voluntary cough function will be assessed using an oral pneumotachograph (MLT 1000, ADInstruments, Inc; Colorado Springs, CO), connected to a spirometer filter (MQ 304 Spirometer Filter, Vacumed; Ventura, CA) during voluntary cough production. The participant will be seated with a respiratory facemask held in place by the examiner and instructed to complete three tidal breaths into the facemask, take a deep breath in and then "cough hard like you have something stuck in your throat". This task will be modeled to the patient by the examiner and practiced first to ensure the patient understands the procedure. Airflow signal will be measured, low pass filtered at 150Hz, digitized at 1 KHz and displayed on a portable laptop computer using Chart Version 7 (Microsoft Corp; Redmond, WA).

Reflexive Cough Testing:

Participants will be outfitted with a facemask covering the nose and mouth. The facemask will be coupled to a pneumotachograph, differential pressure transducer, and have a side port with a one-way inspiratory valve for nebulizer connection. The nebulizer will be a DeVilbuss T-piece connected to a dosimeter that delivers aerosolized solution during inspiration with a delivery duration of 2 seconds. The cough airflow signal will be digitized (Power Lab Data Acquisition System) and recorded (LabChart 7; ADInstruments, Inc) to a computer for offline analysis. Participants will be seated for an initial 30 seconds of quiet breathing in order to acclimate to the facemask. Participants will then complete a capsaicin challenge with three randomized blocks of 0, 50, 100, 200, and 500 µM capsaicin. The capsaicin will be dissolved in a vehicle solution consisting of 80% physiological saline, and 20% ethanol. Participants will be given the instruction "cough if you need to" prior to capsaicin delivery. The solution will be administered automatically upon detection of an inspired breath and there will be a minimum of one minute between each trial. After each inhalation of the capsaicin solution, participants will be asked to rate their urge-to-cough (UtC) on a modified Borg scale, ranging from 0 (no urge to cough) to 10 (maximal urge to cough). Participants will be provided water to drink between trials. Members of our research team have extensive experience using this methodology for the induction of reflex cough (Hegland et al., 2012; Wheeler-Hegland et al., 2014), and we have a FDA IND # 76866 for the use of capsaicin in the study of cough reflex sensitivity and motor pattern.

<u>Data Collection Procedures</u>

The principal investigator will be responsible for safety and monitoring data (oversight plan). The data will be collected and recorded by the principal investigator and her research assistants who will enter data into the research database. Data will be kept in

a locked cabinet within a locked laboratory. All data entered into the database will be coded to remove participant identifiers and this database is backed up daily. Data accuracy will be verified by double data entry. That is, following initial data entry the research assistant and /or principal investigator will verify the data entered into the database. Data verification will take place prior to any analysis of these data. Data, adverse events and individuals subject safety will be routinely monitored throughout each subject evaluation by the PI. A regulatory binder will be kept, in accordance with the IRB-01 Researcher Tools. Any adverse event will be immediately reported to the IRB (using Regulatory Serious and Adverse Unexpected Event Form). Early closure of the study may occur if the team is unable to enroll subjects, or subsequent to unexpected adverse events. However, neither of the events are anticipated.

Risks/Benefits Analysis

- This research study involves exposure to radiation from x-rays. The radiation exposure you will receive from the swallowing test (videofluoroscopy) is about 50 millirem. This radiation exposure is equivalent to 60 days 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.
- 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.
- Barium will be the material used to help us see your swallow function and sometimes when testing is done the barium may enter your lungs during swallowing causing you to cough or feel some discomfort. While small amounts of barium ingested into the lungs does not pose a significant health risk, large amounts ingested over several days can lead to aspiration pneumonia, which is a bad respiratory infection. Therefore, we will stop the test if we see barium enter the airway on more than two swallows of liquid or food to prevent major health risk.
- The ‘hot pepper’ vapor we will use to make you cough during this part of the testing contains capsaicin, which comes from hot peppers. It may cause a hot sensation in your mouth and throat. This will go away within a few seconds after you stop inhaling breathing the capsaicin vapor. Water will be available to you whenever you want it.

- Although not common, it is possible that you will experience jaw and throat muscle soreness after you are done completing the tongue strength and endurance trials. This discomfort should be temporary and subside within 48 hours.

Outcome Measures:

This study has several outcome measures because the goal is to establish normative parameters for a variety of clinical tests. The outcome measures include: maximum expiratory/inspiratory pressures (MEP/MIP), which will be assessed using a hand held digital manometer (Micro Mouth Pressure Meter, MP01, Micro Direct Inc.). In order to measure MEP, the participant will be seated with the nose occluded with a nose clip. After inhaling to total lung capacity, the participant will place his or her lips around a disposable mouthpiece and blow out as forcefully as possible. Numbers are then recorded with the maximum across all three trials used for data analysis purposes.

Additional outcome measures include maximum effort results from: high resolution manometry (pressure recordings), swallowing timing and kinematics (swallow study) and tongue pressure recordings (tongue testing). The procedures of these tests are described above.

Data Analysis

Data analysis will be primarily descriptive, including central tendency, range and standard deviation in order to determine average values for each of the completed tests. This will help to create the database for normative parameters for swallowing and respiratory tasks.

Limitations

It is possible that there may be a limitation in the age range of the sample size, as we are recruiting from a university setting. There are no other known limitations to the present study.

Implications

This study will provide researchers and clinicians with the data to compare disordered populations with normative parameters across clinical testing procedures. The results will contribute to evidence for identifying disorder and subsequently recommending certain swallowing therapy approaches.

None of the study members on this team have a financial interest or conflict of interest.

References

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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 that 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?

Establishing Normal Swallowing and Breathing Profiles in Healthy adults across the age span

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

Principal Investigator: Dr. Emily Plowman, Ph.D., CCC-SLP (352)-273-9215

Other research staff:

Jennifer Chapin, M.S., CCC-SLP (860) 798-5009

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Danuza Nunn, M.S., CCC-SLP (617) 852-0957
Raele Robison, M.S. (610) 504-4605
Alicia K. Vose, MA CCC-SLP (860) 912-8156

4. Who is paying for this research study?

The sponsor of this study is the National Institute of Health, Department of Speech, Language and Hearing Science, College of Public Health and Health Professions at the University of Florida, and the Clinical and Translational Science Institute Pilot Research program.

5. Why is this research study being done?

The purpose of this research study is to understand the normal function of swallowing and respiratory muscles in order to establish normal parameters. This will allow us to compare normal physiology and function of the swallowing and respiratory muscles to the performance of individuals with neurodegenerative disease and stroke. It is also to identify clinical tests that are quick and easy to administer in a clinical setting. Volunteers are being asked to participate in this study in order to better understand normal swallowing and breathing function in order to develop treatments for individuals with swallowing and breathing impairments.

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.

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)?

Nothing. Normal clinical care is medical or treatment or services that you would receive even if you did not participate in this research study.

Participation in this study is not part of your normal clinical care and your normal clinical care will not be impacted regardless of whether you to choose to participate in this study or not.

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

Screening: Adults who are pregnant, or those with major medical conditions (i.e., swallowing impairment, brain injury, deviated septum, G.I. strictures obstructions, or Zenker's diverticulum, surgeries to nose, neck or throat or bleeding disorders) will be excluded from this study. Anyone with allergy to barium or lidocaine will be excluded

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from this study. Those in the Communication Science Disorder field or have learned about their swallowing before should be excluded. Individuals with difficulty following directions, or uncorrected visual impairments shall be excluded. No specific gender or race will be excluded or targeted for participation in this study. To help the study personnel determine if you are eligible for the study, women who are considered to be of childbearing age (less then 62 years) will be asked to complete a pregnancy test to confirm they are not pregnant prior to performing the exam.

Examinations: Participants in this study will be asked to attend one or more (up to four) appointments. You are being asked to attend _____ appointment/s at the University of Florida Swallowing Systems Core Laboratory located at Shands Hospital, Gainesville, Florida. Each appointment is expected to take approximately 90 minutes to complete. The specific testing that you are being asked to complete is checked in the list below.

____ **Swallowing X-Ray Study:** You are being asked to complete an X-ray of your swallowing, this is called a Video fluoroscopy and is like a movie x-ray of you swallowing foods and liquids. For this test you will be asked to sit comfortably in a chair and swallow barium. Barium is a substance that allows us to see how food and liquids flow through your mouth, throat, and esophagus during x-ray. It is white to the naked eye but appears black in the x-ray. Barium may be thin, liquid, nectar, honey, or paste consistencies. You cannot feel the x-ray while it is on and the total time that the x-ray machine will be on will be under five-minutes (although the test will take approximately ten-minutes).

We will ask you to swallow in three ways: First we will ask you to swallow using traditional cup sips of various volumes and consistencies. Secondly, we will place liquid in the front of your mouth and give you a "go" signal to swallow; and lastly, another will involve placing the liquid in the back of your mouth and into your throat with a tube that sits in a mouth piece we make for you. The mouth piece is made with standard dental putty. We will ask you to try to swallow in one gulp. Sometimes we will provide you with visual and/or sound cues for when to swallow. If you are uncomfortable with any of these procedures at any time we will stop them immediately.

We will ask you to swallow while moving your head in different directions (i.e. turning to the left or right, head back (chin up) or down). We will also ask you to swallow with your head in your regular neutral position.

____ **High Resolution Manometry:** You are being asked to complete high resolution manometry testing where we will be using a small pressure tube that gets inserted into the nose and travels down to the back part of the throat. After the tube is in place in the throat, the subject will sit comfortably for five minutes to acclimate to the tube being in this position. After this time, they will be asked to swallow water or barium. They may feel a slight discomfort as the tube is being placed in position and as they begin to swallow the water or barium with the tube in place. Time to complete all swallowing-related tests will be approximately 30

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minutes and participation in this study will require only one visit. Individuals have the option to decline this procedure if uncomfortable or difficult to tolerate.

____**High Resolution Impedance Manometry**: You are being asked to perform impedance manometry where we will be using a small pressure tube that gets inserted into the nose and travels down to the back part of the throat.

After the tube is in place in the throat, the subject will sit comfortably for five minutes to acclimate to the tube being in this position. After this time, they will be asked to swallow a saline solution. Saline is a thin-water like solution that has a slightly salty taste. They may feel a slight discomfort as the tube is being placed in position and as they begin to swallow the saline with the tube in place. Time to complete all swallowing-related tests will be approximately 30 minutes and participation in this study will require only one visit. Individuals have the option to decline this procedure if uncomfortable or difficult to tolerate.

____**Pulmonary Function Testing:** We will ask you to perform a series of respiratory related maneuvers. First, we will ask you to take a deep breath in and blow out fast and hard into special device called a manometer, which is designed to record the pressure of this exhalation. Next, we will ask you to blow out all of your air and then quickly breathe in using the same, special device to measure your maximal inhalation pressure. Using a different respiratory device (a spirometer) we will ask you to take a deep breath in and blow out your air slow and steady into this equipment to measure the total amount of air volume your lungs can exhale. You may be asked to repeat these measures several times during the evaluation. There is no compensation for this test.

____**Cough Testing:** We will also ask you to cough into special equipment to measure your cough strength and ability to detect irritants in your airway. For one part of the cough testing we will have you breath in and out of a nebulizer that will contain increasing concentrations of a hot pepper vapor that will make you cough. There will be a minimum of 1-minute rest time in between the cough trials and you will be offered water as needed. There is no compensation for this test.

____**Tongue Pressure Examination:** During the tongue examination, we will measure your tongue strength and the maximum amount of time that you can apply pressure to an air-filled tongue bulb that will rest on the roof of your mouth. There is no compensation for this test.

____**Surface Electrical Stimulation***:* Surface Electrical Stimulation: Electrical stimulation is a widely-used treatment for dysphagia in the United States. Data be acquired with surface electrodes placed on the face and/or neck using the Dual Bio Amp (AD Instruments). All swallows in this study will be recorded with surface electrical stimulation for comparison with Video Fluoro Data. Surface electrical stimulation can be uncomfortable. We will only administer electrical stimulation at an intensity that is tolerable. It can also be dangerous for individuals with a pacemaker or any other foreign, permanent metal in the head and neck (excluding dental work) because the metals can become very hot or

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interfere with their function. We are excluding these individuals. We will screen all patients to ensure that they do not have contraindications (pace-maker, foreign metal in the neck, open skin wounds) prior to administering e-stim. During surface electrical stimulation we will place some small electrodes on the surface of your skin underneath your chin. These will measure the activity of the muscles under that skin.

We will use an alcohol wipe to clean the skin before placing the electrode. If you a male, we ask that you are clean-shaven so that the electrode can make good contact with that skin. We will also place a thin strap around your neck loosely. We will stimulate the muscles of your neck and under your chin with a therapeutic rehabilitation tool called electrical stimulation. You might feel a prickly sensation on your skin and you will feel your muscles contract. You will decide the strength of the stimulation, which should not be painful. We will only administer electrical stimulation at an intensity that is tolerable. These will measure the activity of the muscles under that skin.

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems.

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?

Participation includes one 90-minute appointment with up to four follow up appointments or contact with participants.

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

Up to 120 persons will participate in this study.

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?

- This research study involves exposure to radiation from x-rays. The radiation exposure you will receive from the swallowing test (video fluoroscopy) is about 50 millirem. This radiation exposure is equivalent to 60 days 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

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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.

- Barium will be the material used to help us see your swallow function and sometimes when testing is done the barium may enter your lungs during swallowing causing you to cough or feel some discomfort. While small amounts of barium ingested into the lungs does not pose a significant health risk, large amounts ingested over several days can lead to aspiration pneumonia, which is a bad respiratory infection. Therefore, we will stop the test if we see barium enter the airway on more than two swallows of liquid or food to prevent major health risk.
- The 'hot pepper' vapor we will use to make you cough during this part of the testing contains capsaicin, which comes from hot peppers. It may cause a hot sensation in your mouth and throat. This will go away within a few seconds after you stop inhaling breathing the capsaicin vapor. Water will be available to you whenever you want it.
- Although not common, it is possible that you will experience jaw and throat muscle soreness after you are done completing the tongue strength and endurance trials. This discomfort should be temporary and subside within 48 hours.
- The manometry catheter, placed through the nose into the throat, may irritate the gag reflex when placed. Although this is a routine clinical procedure, this may be uncomfortable. This discomfort should be temporary and this procedure may be stopped at any point in time.
- Allergies to the following substances may prevent you from participation in the modality in which the substance is used. Barium allergies will prevent participation in Swallowing X-Ray Study. Capsaicin allergy will prevent participation in Cough Testing. Lidocaine allergy will prevent the optional use of lidocaine during manometry, but not prevent the manometry testing.
- During surface electrical stimulation we will place some small electrodes on the surface of your skin underneath your chin. These will measure the activity of the muscles under that skin. We will use an alcohol wipe to clean the skin before placing the electrode. If you a male, we ask that you are clean-shaven so that the electrode can make good contact with that skin. We will also place a thin strap around your neck loosely. We will stimulate the muscles of your neck and under your chin with a therapeutic rehabilitation tool called electrical stimulation. You might feel a prickly sensation on your skin and you will feel your muscles contract. You will decide the strength of the stimulation, which should not be painful. These will measure the activity of the muscles under that skin.

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

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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.

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.

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

You will not personally benefit from participation in this study.

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

Depending on the results of this study, we may be able to recommend procedures to be used by healthcare providers working with persons that have neurodegenerative disease or stroke and identify and manage swallowing problems earlier.

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.

None of the study members on this team have a financial interest or conflict of interest.

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

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

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 one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

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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 choose to withdraw from this research study, we will no longer collect new information about you. We will use information that was collected prior to your withdrawal from the study. This information may have already been shared with others or we may need it to complete and protect the validity of the research.

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

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

- In the event the study team members believe participation is adversely affecting your health.
- If you are diagnosed with another medical illness that may make it difficult to establish normative parameters.
- You are unable to completed the tasks (cannot perform the cough or tongue pressure trials as required)
- The study is canceled.

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 Services

The Sponsor will pay for all medical services activities required as part of your participation in this study as described above in the question "What Will Be Done Only Because You Are In This Research Study". If you receive a bill for these services, please contact Dr. Emily Plowman at 352-273-9215.

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 compensation depending on the assigned procedures listed above for your time participating in the study. Compensation for each eligible procedure is $30, for total compensation of up to $120.

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

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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.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

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 Dr. Emily Plowman at 813-990-7095 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

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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:

- Your entire research records (swallowing x-rays, surveys, training logs)
- Name and contact information (home and email addresses, phone number)

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):

- Ensure that you meet the preset criteria to participate in research.
- Establishing normative data for comparison with disordered populations.

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).

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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 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. After the entire study has finished, your PHI will be stored in a secure location and your records will be purged after three years.
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.

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Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, _____, or her successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date

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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