# James Madison University

Human Research Review Request

**For IRB use only:**

Exempt: ☐ Expedited: ☐ Full Board: ☐

**Protocol Number:** IRB- _____ Received: _____

1st Review: _____ 2nd Review: _____ 3rd Review: _____

**Reviewer:** _____ **Reviewer:** _____

**Responsible Researcher(s):** Christy L Ludlow, PhD
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**Department:** Communication Sciences and Disorders
**Address (MSC):** 4304

**Please select:** ☒ Faculty ☐ Undergraduate Student ☐ Administrator/Staff Member ☐ Graduate Student

***(If Applicable):***
**Research Advisor:** _____
**E-mail address:** _____
**Telephone:** _____
**Department:** _____
**Address (MSC):** _____

**Project Title:** The Passy Muir Swallowing Self Training Device to Enhance Recovery Post Stroke

**Project Dates (Cannot exceed 1 year minus one day):** From: 08/01/12 MM/DD/YY To: 07/31/13 MM/DD/YY

**Minimum Number of Participants:** 30
**Maximum Number of Participants:** 45

**External Funding:**
Yes: ☒ No: ☐
If yes, Sponsor: Passy Muir, Inc., subcontract from SBIR awarded by the National Institutes of Health

**Investigator: Please respond to the questions below. The IRB will utilize your responses to evaluate your protocol submission.**

**1.** ☒ **YES** ☐ **NO** Does the James Madison University Institutional Review Board define the project as ***research?***

The James Madison University IRB defines "research" as a "systematic investigation designed to develop or contribute to generalizable *knowledge*." All research involving human participants conducted by James Madison University faculty, staff, and students is subject to IRB review.

**2.** ☒ **YES** ☐ **NO** Are the human participants in your study ***living*** individuals?

"Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains:
(1) data through intervention or interaction with the individual; or (2) identifiable private information."

**3.** ☒ **YES** ☐ **NO** Will you obtain data through ***intervention*** or ***interaction*** with these individuals?

"Intervention" includes both physical procedures by which data are gathered (***e.g.***, measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and participant (***e.g.***, surveying or interviewing).

**4.** ☒ **YES** ☐ **NO** Will you obtain ***identifiable private information*** about these individuals?

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (*e.g.*, a medical record or student record). "Identifiable" means that the identity of the participant may be ascertained by the investigator or associated with the information (*e.g.*, by name, code number, pattern of answers, etc.).

**5.☐ YES ☒ NO** Does the study present ***more than minimal risk*** to the participants?

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well-being, social standing, and risks of civil and criminal liability.

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**CERTIFICATIONS:**

For James Madison University to obtain a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services, **all** research staff working with human participants must sign this form and receive training in ethical guidelines and regulations. "Research staff" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors. The Office of Sponsored Programs maintains a roster of all researchers who have completed training within the past three years.

**Test module** at OSP website http://www.jmu.edu/sponsprog/irb/irbtraining.html

| Name of Researcher(s) | Training Completion Date |
|---|---|
| Christy L. Ludlow | 06/05/2010 |
| Erin Kamarunas, PhD | 08/06/2013 |
| Carrie Jones, M.S. | 02/06/2013 |
| | |
| | |

For additional training interests visit the National Institutes of Health Web Tutorial at: *http://cme.nci.nih.gov/*

By signing below, the Responsible Researcher(s), and the Faculty Advisor (if applicable), certifies that he/she is familiar with the ethical guidelines and regulations regarding the protection of human research participants from research risks. In addition, he/she agrees to abide by all sponsor and university policies and procedures in conducting the research. He/she further certifies that he/she has completed training regarding human participant research ethics within the last three years.

_____ _____
Principal Investigator Signature Date

_____ _____
Principal Investigator Signature Date

_____ _____
Principal Investigator Signature Date

_____ _____
Principal Investigator Signature Date

_____ _____
Faculty Advisor Signature Date

Submit an electronic version of your **ENTIRE** protocol to jmu_grants@jmu.edu.
Provide a **SIGNED** hard copy of the Research Review Request Form to:
Office of Sponsored Programs, MSC 5728, James Madison Administrative Complex, Bldg #6, Suite 26

Following are the components for a complete research protocol. Please use this template to complete your protocol for submission. Each category must be addressed in order to provide the IRB sufficient information to approve the research activity. Please use as much space as you need, but adhere to the overall **10-page limitation**.

**For additional detail on each category, see:**
**http://www.jmu.edu/sponsprog/irb/irbsubmit.html**

**Background and Objectives**

*Patients with dysphagia have limited access to swallowing rehabilitation*: Fifty percent of patients post stroke have swallowing difficulties with risk of aspiration[7]. If aspiration continues, with the passage of food or liquids through the larynx and into the lungs, it can cause an infection leading to pneumonia. Many hospitals screen acute stroke patients for risk of aspiration before allowing them to take medications and nutrition orally[8]. When there is evidence of aspiration, patients are designated nothing per oral (NPO) requiring a nasogastric tube for nutrition during acute hospitalization. Patients are referred to a speech pathologist to evaluate whether diet modification (use of thickeners) or compensatory strategies (head turn or chin tuck) will allow safe oral intake. Evidence on the effectiveness of these interventions is limited[2]. Hospital discharge post stroke is within days mostly to home (~50%), a skilled nursing facility (SNF ~25%) or inpatient rehabilitation (~20%)[9]. Before discharge those who are not able to swallow safely receive a percutaneous endoscopic gastrostomy (PEG) tube to support nutritional intake[10, 11]. Unfortunately recommendations for dysphagia management including therapy are often not included in discharge orders, limiting further care[12]. Subsequent access to rehabilitation is limited and patients' swallowing problems are not further addressed unless they develop aspiration pneumonia and are re-admitted to hospital (estimated at 27%)[11]. Therefore, thousands of patients each year continue to have untreated dysphagia with reduced survival[11], decreased quality of life and a lifetime of impaired nutrition.

The Passy Muir Swallowing Self-Trainer (PMSST) will Continue Swallowing Rehabilitation beyond Inpatient Status Without Additional Cost. This device and method for self training will allow patients with dysphagia to continue therapy in their own environment with the potential for recovery of safe swallowing. A speech pathologist will introduce the device and train the patient prior to discharge from hospital or inpatient rehabilitation so the patient can continue their therapy at home. Training will use small controlled amounts of water (~2-5ml) which have been shown to be safe[13]. Self retraining involves: 1) oral administration of a small amount of water, 2) the patient pressing a hand control to turn on sensory simulation, and 3) the patient immediately attempting a volitional swallow (Figure 2). Up to 300 practice swallows occur each day; 60 are self training swallows when the patient uses the stimulator to practice volitional swallows while 240 swallows are provided during waking hours when the device cycles on automatically for a few seconds every 3 to 5 minutes to induce saliva swallowing.

The significance of this home based patient-centered swallowing training is multi-dimensional. It will interrupt the usual cycle of recurrent aspiration leading to pneumonia and allow patients to regain oral nutritional intake after discharge to home. Patients on PEG tube feeding require costly care to maintain nutrition and prevent hospital readmissions due to aspiration pneumonia. *Self training will overcome access and cost barriers to continued rehabilitation, allow patients to receive swallowing therapy long-term, and enhance the speed and extent of recovery.* With further worldwide increases in the aging population expected to accelerate health care costs, the reallocation of intensive rehabilitation to the patient in their environment, will increase recovery while reducing costs. This is in synchrony with world trends for patient-centered community based models providing a continuity of chronic care beyond hospitalization[14].

**Purpose**

The purpose of this research is to define the optimal characteristics of the device to be developed prior to future research in Phase 2. The purpose here is **not** to evaluate the usefulness of the self training device, that will be done in Phase 2. In this Phase 1 study we are only trying to identify the optimal characteristics of the device to be developed before using it as a self training device in Phase 2.

**Procedures/Research Design/Methodology/Timeframe**

**Research Design Aim 1:**

Subjects: Patients with dysphagia post stroke will be recruited from the VS-CRF and inpatient and outpatient admissions post stroke. The videofluoroscopic records of patients who volunteer will be reviewed to determine if they have a score of 2 or greater on the Pen-Asp scale[47]. Those without a videofluoroscopic study will receive the Mann Assessment of Swallowing Ability to identify those with a severity rating of "mild" or greater, that is a total numeric score of 177 or less [48, 49]. If a nasoendoscopic evaluation of swallowing has been conducted, that will also be reviewed to determine if there is evidence of risk of aspiration[50]. (see Human Subjects protection).

i.Frequency Comparisons:
Motors at frequencies of 30, 70, 110, 150, and 70/110 Hz (using 2-6 kPa neck pressure) will apply 8 s of stimulation followed by 15 s rest for a total of 28 stimulation trials for a total of 10.7 minutes per condition. Optionally, other hybrid motors similar to the 70/110 Hz motor may be used. After a condition, the patient will mark on a visual analogue scale of 0 to 100 mm their *urge to swallow* and their comfort level with stimulation for that condition. Online recordings of bi-axial accelerometry of laryngeal motion, inductive plethysmography of respiration, and digital video recordings will identify laryngeal movement and respiratory apnea to confirm swallows (Figure 4). Swallows cannot be identified during stimulation because of vibration interfering with the accelerometry signals, which necessitates video recording. The *rate of swallowing* in a 10.7 minute condition will be computed. The order of different frequencies will be counter-balanced across patients. Total testing time with rest periods will be 1 hour. If all the frequencies cannot be tested in the one hour time period, the remaining untested frequency (ies) can be completed at the end of another session if time allows, or the participants can attend additional sessions as needed. We expect that one frequency will be optimal across patients; if two frequencies are optimal we will combine them by using motors with different frequencies on each side.

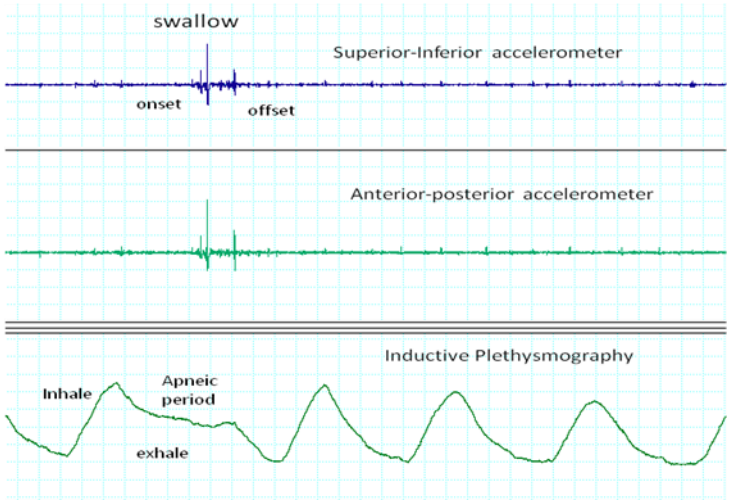

Figure 4 Identification of swallows using accelerometry of laryngeal movement, sum signal of inductive plethysmography (ip), and the first derivative ip to identify swallow onset and offset, exhalation and the apneic period

ii.Mode Comparisons: Using the optimal frequency(ies) identified, we will compare the effects of continuous versus the 4 Hz pulsed modes for 10.7 minutes each in counter-balanced order across patients measuring the rate of swallowing and ratings of the urge to swallow to identify the most effective mode of stimulation.

iii. Pressure Comparisons: Using the Iowa Oral Performance Instrument to measure strap to neck pressure and calipers to measure neck tissue fat, the effects of 2, 4, and 6kPa on rate of swallowing and urge to swallow with 8 s stimulation at the optimal frequency and mode of stimulation will be measured.

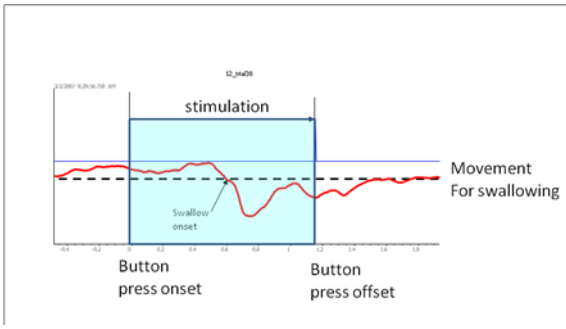

Figure 5. Display to patient training to provide stimulation onset within 500 ms before swallowing

iv. Stimulation Duration: We will determine the stimulation durations applied by patients when they are instructed to initiate swallowing during stimulation using the parameters identified for stimulation in i, ii and iii. The time required for them to

initiate swallowing after the onset of stimulation will be measured using air filled bellows wrapped around the neck to identify swallowing timing after stimulation onset (Figure 5). Air filled bellows are required as vibratory stimulation will interfere with accelerometry; we have used these bellows previously to identify swallowing in fMRI[42]. Additionally oral pressure sensor in ~~using~~ a small tube placed on the anterior tongue ~~will~~may be used to identify swallows. Neck calipers will measure tissue thickness in the throat area overlying the thyroid cartilage which may affect sensory input. When the participant has completed their final session, they will mark on a visual analogue scale of 0 to 100 their level of interest in using the self-training device at home for swallowing therapy.

Expected Outcomes and Power Analyses: For each of the 4 experiments we will compare the mean visual analogue score and the mean swallowing rate within patients across conditions. Based on previous studies in healthy volunteers contrasting air puff stimulation on the rate of swallowing by Theurer et al.,[38, 51], the expected change in rate of swallowing will be from 1.2 swallows/minute without stimulation to 2.0 with stimulation with a standard deviation of the differences being 0.9. Using a Bonferroni corrected alpha of 0.025 (to test 2 measures) at 0.80 power with an effect size of 0.88, the number of patients needed will be 15 per experiment. Allowing for some patients to participate in several studies, we plan to recruit between 30 and 40 patients with risk of aspiration post stroke to participate in Aim 1 (see Human Subjects section).

Potential Problems and Alternative Strategies: Anticipated problems include difficulties with recruiting an adequate sample of patients in the Harrisonburg area for testing in our clinic at RMH. Over 412 patients were admitted to RMH acute post stroke in 2010 and the number is increasing each year while many more come for outpatient rehabilitation. We have 3 rooms in our JMU-RMH VS-CRF to support multiple patients being tested simultaneously. All equipment can be portable including Powerlab, a laptop, the amplifier system, the Kistler accelerometers and Inductive plethysmography so we can also test patients in rehabilitation and skilled nursing facilities throughout the Shenadoah valley. The 2011 Healthy Community Survey found that 20 percent of seniors in the Harrisonburg area have had a stroke out of an estimated 120,000 total population. Therefore access to 40 post stroke patients with dysphagia is feasible. In addition, we have developed a website, NetMedSLP, serving speech pathologists in medical settings throughout Virginia. This site provides continuing education to speech pahtologists specializing in dysphagia in Virginia. Over 2 dozen speech pathologists are registered and we intend to use this website to recruit collaborating speech pathologists for patient referral for our research studies. Further, Passy Muir employs 2 respiratory therapists in Virginia who can access speech pathologists to assist with patient recruitment. Future Directions These studies will be the basis for designing a prototype device for swallowing retraining by patients with dysphagia post stroke for Phase II.

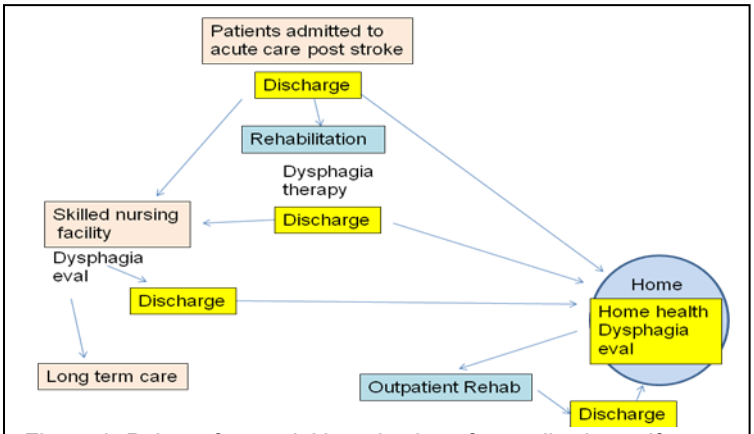

Figure 6. Points of potential introduction of a swallowing self re-training methods and device to patients post CVA are in yellow.

**Aim 2. Identifying Delivery Points for Introducing Patients to Swallowing Self-training.**

**Background** The Passy Muir Swallowing Self-Training device is a novel approach to dysphagia rehabilitation. It requires that speech pathologists are willing to augment a patient's rehabilitation by introducing a self-training device before discharge to home. As the majority of patients return home in the care of a family member post discharge[9], the time before they are discharged is optimal for introducing a self re-training device as shown in Figure 6. Aim 2 is to obtain input from speech pathologists on the optimal time and method for introducing a swallowing self-trainer for patients with dysphagia post stroke. Speech pathologists' input on the development of methods for patient introduction and training is needed prior to Phase II. Points of discharge to home, either from acute

care, skilled nursing or rehabilitation are time points to introduce a home based self-training system to patients who continue to have swallowing disorders post stroke.

Will data be collected from or about any of the following populations?

_____ Minors (under 18 years of age); Specify Age: _____
_____ Prisoners
_____ Pregnant Women
_____ Fetuses
_____ Cognitively impaired persons
X_ Other protected or potentially vulnerable population
_____ Not Applicable

Humans Subjects protections information

**Revised Human Subjects Protection for Aim 1: Identifying the optimal stimulation characteristics for increasing swallowing in dysphagic participants (Subcontract with James Madison University)**

**Risks to Human Subjects**

***a. Human subjects involvement, characteristics and design***

Participants in the subcontract at James Madison University will include up to 40 adults who have been diagnosed as having a swallowing disorder following a stroke. Based on the Harrisonburg Health Community Survey 2011, it is estimated that 20% of seniors have had strokes in the Harrisonburg community, 2/3 of who are male. Figures from the U.S. Census 2011, and the *Virginia Atlas 2005* indicate that the population breakdown by race and ethnic categories are 78% Caucasian, 6% African American, 4% Asian, 16% Hispanic and 12% Other in the Harrisonburg area. We used these estimates in completing our enrollment table.

The criteria for inclusion will include diagnosis of an oropharyngeal swallowing disorder (dysphagia) post stroke on instrumental examination including videofluoroscopy. We will limit recruitment to those persons who meet specific criteria for swallowing disorders based on published screening instruments (described below). We will recruit persons to come for screening or visit their home if that is more convenient for them. All participants will have had a modified barium swallow study within one year prior to participation in the study. If a participant has had a videofluoroscopic examination within the last year and is stable we will review that examination or the description to determine if they would have a score of 2 or greater on the Pen Asp Scale[1]. This scale can be obtained from review of a videofluoroscopic examination and is the gold standard method of measurement of risk of aspiration. We will also use the Mann Assessment of Swallowing Ability (MASA) to screen for persons who continue to have dysphagia [2], recently found to have the highest sensitivity and specificity for identifying participants with aspiration on videofluoroscopy[3]. By including only participants with a Pen Asp score of 2 or greater or a MASA numerical score of 177 or less, only participants with mild or worse oropharyngeal dysphagia will be included in this research. A nasoendoscopic evaluation of swallowing may be administered if required for clinical care and ordered by a physician[4]. Participants will be carefully selected to only include those with some upper esophageal sphincter (UES) opening on videofluoroscopy to avoid including participants who would accumulate significant residue during the testing. Exclusions from the research will be participants with no UES opening, and other disorders such as traumatic brain injury, Parkinson disease, post head and neck surgery for cancer, chemoradiation for head and neck cancer, or a history of other events that could have affected neuromuscular innervation of the swallowing musculature such as coronary bypass, cervical spinal fusion or brain stem tumor excision. Participants with more than one stroke can be included.

As the primary aim of this study is to gather participants' feedback on their preferences regarding device characteristics regarding frequency of vibration, continuous versus pulsed modes of vibration, pressure of the device on the skin surface, and duration of stimulation, participants will need to be able to communicate their preferences to the investigators when they participate for one hour sessions in the hospital clinic. They will need to indicate their visual analogue scale ratings and communicate their

preferences verbally. Therefore, a speech pathologist will administer the Folstein Mini-Mental State Examination (MMSE) and require a score of 23 or greater for inclusion in the study. We have previously found that this assures adequate understanding in participants in such a study. Any patient unable to meet these criteria will not be included in the research as they will not be able to provide accurate feedback and fully understand the purpose of the study. As only patients capable of understanding the purpose of the study and participating in the informed consent process, no permission will be obtained from a guardian or power of attorney.

Assignment to Studies. Participants will be recruited into the studies planned for Aim 1 in the order that we conduct the studies. The first study, study i, will compare the effects of motors at frequencies of 30, 70, 110, 150, 70/110 Hz, and other similar hybrid motors and measure the degree of *urge to swallow*, comfort level and frequency of swallowing during intervals following stimulation. To identify swallowing, noninvasive recordings will involve of bi-axial accelerometry of laryngeal motion, inductive plethysmography of respiration, and video recordings will identify laryngeal movement and respiratory apnea to confirm swallows. Total testing time for this first study will not exceed 1 hour; if a participant becomes fatigued we will stop the testing. Fifteen participants will be recruited and tested to evaluate different motor frequencies in study i. The testing for study ii comparing continuous versus pulsed stimulation will be conducted along with study iv determining how long stimulation is needed for a participant to initiate swallowing after stimulation, as these two studies combined will require about 1 hour. These studies will also involve 15 participants, some of who may have participated in study i. Finally, study iii will also require no more than 1 hour and will compare the effects of different neck band pressures in 15 participants some of whom may have participated in studies i, ii or iv.

We will try to accommodate participants' needs and prevent fatigue or inconvenience by dividing up the testing conditions or conducting the testing in their home if they prefer. All of our equipment is portable, including suctioning, which will allow us to travel to the participants' environments either at home, or in a nursing or rehabilitation setting. Only nasoendoscopy is restricted to the hospital environment and will only be conducted if ordered by a physician.

During this Phase I SBIR research, the participants will not be using the device for swallowing training, rather they will only be asked to wear the device for short periods of 10 minutes and only saliva swallows will occur which normally occur throughout the day. Stimulation periods of 5-10s will occur intermittently over 10.7 minutes followed by a break when we will change devices. During breaks the most severely affected participants who have difficulty swallowing their saliva will either have their secretions suctioned or will expectorate their saliva into a cup. By suctioning as needed between stimulation periods, the participants' secretions will be managed throughout the testing.

***b. Sources of materials.***

Online digitizing will use AD instruments Powerlab and Chart software to record accelerometry on the neck measuring laryngeal movement onset and offset, inductive plethysmography recordings of chest wall and abdominal respiratory movement to identify swallows along with the apneic period, and digital video recordings during each session to visually confirm swallows during data analysis. These recordings will be identified only by ID number and stored as Chart files for analysis on encrypted computers or the secure server in the laboratory at JMU accessible by VPN from laptops in the Voice and Swallowing Service. Analyses can also be conducted on workstations in the Laboratory of Neural Bases of Communication and Swallowing at JMU and only identified by ID code with no personnel health Information (PHI). All video recordings, will be kept for 2 years on an encrypted computer and then destroyed. All deidentified case report forms will be kept for 2 years on a secure server and then destroyed.

Participant visual analogue scale ratings of urge to swallow will be measured and entered into the data base. The responses will be identified by ID code with no PHI.

***c. Potential Risks***

There are only minimal risks to participants in this research. The Phase I studies for the SBIR are short term acute studies aimed at comparing the effects of different vibratory frequencies, pulsed and continuous stimulation modes, changes in neck pressure on participants' frequency of swallowing, their initiation of swallowing and their ratings of urge to swallow during 3 or more short experiments lasting about 1 hour each. During this Phase I SBIR research, participants will **not** be using the device for

swallowing training. Rather participants will only be asked to wear a device for short periods of 10 minutes and provide feedback on their preferences. There are 4 short experiments and participants will be able if they choose to participate in one or more of the studies. The studies will require less than 1 hour of time; a participant may choose to participate in one or more studies during a single visit and could likely complete all of four studies in three or more visits of no more than one hour each.

This study will not involve giving participants any food or liquid to ingest, Rather, the participants will only be swallowing their own saliva which they do in their daily living throughout the day. Therefore, the participants will not have increased risk as only saliva swallows will occur during the study which normally occur throughout the day. Therefore, these studies will involve only minimal risk to participants. The studies will be conducted by a licensed speech-language pathologist.

We will take great care to make certain that all participants and their family or caregivers do not misinterpret the aim of the study as only to provide feedback on device preferences and that we will not be providing treatment for their swallowing disorder. It will be made clear to the participant and caregivers in study notices and advertisements, the informed consent and discussions. They will be told that the purpose of the study is only to gain feedback on a device that is being developed which will eventually be used for self training but that this study does not involve self training or treatment.

Because certified and state licensed speech pathologists will be conducting the research they will provide participants and their caregivers with referral to patient services in their area for treatment of their swallowing disorder if appropriate.

Many of the participants may have an ongoing risk of aspiration in their daily regimen because of their swallowing disorder. The speech pathologists will provide all participants and their family member or caregivers with advice on how to lessen their daily risk of aspiration. (see protections from research risks).

Risk of loss of confidentiality will be prevented by following HIPAA regulations and further protections (see below).

**Adequacy of Human Subjects protection**

***a. Recruitment and Informed Consent***

Participants will be recruited through the James Madison University (JMU) and Rockingham Memorial Hospital (RMH) Voice and Swallowing Service, advertisements in the local newspaper, the Home Health Agencies of Rockingham Memorial Hospital and Augusta Medical Center, Harrisonburg Health and Rehabilitation Center, Rockingham Memorial Hospital Rehabilitation Center and community health care support groups in Harrisonburg including: The Health Place, Caregiver Chat Support Group, Friends and Relatives of Nursing Home Residents Support Group, and the Harrisonburg Community Health Center. We will recruit persons from the Rockingham Memorial Hospital inpatient and outpatient services by placing advertisements in the waiting areas and asking professionals including neurologists, otolaryngologists and speech-language pathologists to place notices in their waiting and office areas. We will similarly ask the RMH Home Health Agency to distribute notices to persons receiving home health services post stroke. We will also place advertisements in both English and Spanish in the Harrisonburg Community Health Center, a local clinic. Notices will also be mailed to professionals involved in stroke rehabilitation in the Shenandoah Valley area asking them to place notices in their waiting and office areas. We will only ask professionals to place notices and make literature available on our study but not to refer patients directly to us so patients will not feel under any undue influence from their caregiver professionals to participate. Our notices and literature will provide information that will allow participants to contact us directly.

We are assured that we will be able to recruit between 30 and 40 participants in order to have 15 participants in each of the 4 studies to reach adequate statistical power. Over 412 patients were admitted to RMH acute post stroke in 2010 and the number is increasing each year while many more come for outpatient rehabilitation. In 2012, the RMH became a recognized Stroke Care Center serving the Harrisonburg area of 120,000 persons. The 2011 Healthy Community Survey found that 20 percent of seniors in the Harrisonburg area alone have had a stroke out of the estimated 120,000 total population.

We have 3 rooms in our JMU-RMH Voice and swallowing Service to support multiple participants being tested simultaneously. The burden to participants coming to our Service is small as they only be

asked to participate in 3 or more visits for one hour each either in their home or at our outpatient service. Free parking is immediately available within 100 ft of the entrance to our testing rooms in the Treatment Center on the ground floor of RMH.

All equipment can be portable including Powerlab, a laptop, the amplifier system, the Kistler accelerometers and Inductive plethysmography so we can also test participants in rehabilitation and skilled nursing facilities throughout the Shenadoah valley. Therefore access to 40 post stroke patients with dysphagia is feasible. In addition, we have developed a website, NetMedSLP, serving speech pathologists in medical settings throughout Virginia. This site provides continuing education to speech pathologists specializing in dysphagia in Virginia. Over 2 dozen speech pathologists are registered and we intend to use this website to notify speech pathologists of our research studies. Further, Passy Muir employs 2 respiratory therapists in Virginia who can assist with patient notification of the research.

Administration of informed consent. Participants will be telephone screened and if they meet the inclusion criteria, they will be mailed the consent form for information purposes to allow them to review it before coming to the Voice and Swallowing Service. The consent will inform participants that Dr. Ludlow has a financial interest in the research. Either Dr. Ludlow or the speech-language pathologist will administer informed consent to the participant. During the consent process, either Dr. Ludlow or the Speech-Language pathologist will review the study with the participant and any family members present to answer questions. The participant will then read the consent and answer a few questions to demonstrate that they understood it. The consent will then be signed, witnessed and a copy given to the participant. Participants who have sight problems will have the consent read to them and a series of questions will be asked of all participants to assure their comprehension of the study before completing the informed consent process. No proxy consent or assent will be accepted for this study.

***b. Protections against risk***

As listed above under Potential Risks, this application is expected to involve only minimal increased risk from the research procedures in post stroke participants with swallowing disorders as only saliva swallows will be evaluated during the experiments. However, as a Phase I safety intervention trial, one purpose will be to determine the degree of risk encountered in patients as a result of device use while participating in the study. All participants will normally be producing saliva and must swallow or expectorate their saliva throughout the day in their normal living. This risk occurs even when they are receiving enteral feeding either through a PEG tube or nasogastric tube.

During the conduct of the device preference studies, speech pathologists will be recording and closely watching participants' saliva swallows. To prevent aspiration of saliva by the participants during the device preference studies suctioning will be continually available to remove accumulated saliva from the oral cavity. Participants will be asked to phonate at regular intervals (every 10 -12 minutes) to detect secretions in the laryngeal vestibule. If the secretions can be heard while the participant is phonating, the participant will be encouraged to regurgitate their secretions into the oral cavity and the secretions will be removed with an oral swipe with a suctioning wand.

All participants are expected to be at increased risk of aspiration in their daily living because of their swallowing disorder independent of the study. The speech pathologists conducting the testing for the research will provide all participants and their caregivers with usual guidance on a daily regimen to follow for preventing aspiration of their own secretions. Each participant will be taught a daily regimen of oral hygiene to minimize oral bacteria. Participants and their caregivers will be taught how to test voice quality during the day in order to detect a wet, gurgly voice quality which would indicate increased fluid in or around the airway. They will be shown how to clear the airway by throat clearing, coughing and spitting into a cup and to clear the airway whenever they suspect increased fluid in or around the airway. All participants and their caregivers will be trained to monitor body temperature daily and contact the research staff if they have a rise in body temperature over three days sequentially while participating in the research. The medical officer for the project, who is not directly involved in the research, will evaluate pneumonia and other medical problems as they arise in participants in the research. It is expected that a participant will be enrolled in the study for about 1 month before being discharged from the study.

If a participant has incidental findings while participating in the research, they will be referred to the medical officer, Ganesh Kini, MD, PhD, FACP, FHM, Medical Director, Hospital Division at

Rockingham Memorial Hospital. Dr. Kini will serve as the medical officer and will evaluate any medical problems as they arise in participants. He will follow internal RMH hospital policies for incidental findings, e.g. providing referrals to specialists, and following state requirements for other incidental findings such as domestic abuse.

During the device preference studies between 5-10 seconds of vibratory stimulation on the neck is applied for up to 28 times within 10.7 minutes for one frequency under the supervision of a speech-language pathologist. Currently we are conducting this study in healthy volunteers in an IRB approved protocol classified as involving only minimal risk by the IRB at James Madison University and the IRB at Rockingham Memorial Hospital. We plan to follow the same procedures involving participants with swallowing disorders post stroke. . The different motors will only be administered to participants under the supervision of the speech-language pathologist during this SBIR Phase I. If the participant is judged to develop increased secretions that they cannot control by swallowing, suction equipment is available in each of the testing rooms of the Voice and Swallowing Service in the hospital to swipe suction to reduce secretions.

If a participant has been designated "nothing per oral", we will not be increasing their risk as we will not be administering food or liquid to participants during Aim 1 testing. We will only be measuring their attempts to swallow their own secretions during the study, which they all must attempt to do throughout the day regardless of PEG tube status.

To protect confidentiality, a participant's personal health information (PHI) will only be retained in a locked file cabinet in the Voice and Swallowing Service with the assigned participant ID code for this research protocol. The informed consents will be scanned into the Rockingham Memorial Hospital electronic medical records system. All other records, data recording and analysis documents will only contain the assigned Participant ID code for the research protocol. The Case Report Forms will only contain the ID code in LabTrack, an electronic notebook system used by Dr. Ludlow's laboratory at JMU on a secure server that meets FDA requirements for data auditing. This system can only be accessed through VPN from laptops in the Voice and Swallowing Service.

**Potential Benefits of the Proposed Research to Human Subjects and Others**

The guidance that will be provided on how to prevent aspiration pneumonia may benefit participants who have not previously received this guidance. No immediate direct benefit will be provided to the participants in the research unless they have not previously had their swallowing disorder identified as they will receive an initial screening for oropharyngeal dysphagia by a speech-language pathologist. Such participants will be referred to the Medical Director of the JMU-RMH Voice and Swallowing Service for examination before they will be included in the research. Otherwise most participants will have previously been evaluated for a swallowing disorder and their participation will not provide them with direct benefit. Participants will be compensated $20.00 for every experimental research session they participate in while enrolled in this study and will be reimbursed for travel mileage to offset the inconvenience of traveling to the Voice and Swallow Service, which participation requires.

Potential benefits from this research are considerable for future patients with dysphagia following stroke. Most patients with dysphagia post stroke do not continue to receive therapy after their discharge to home or a skilled nursing facility and are restricted in swallowing if they are at risk of aspiration pneumonia. The development of a self-training system will allow such patients to continue to receive therapy for their swallowing disorder after discharge from the hospital or a rehabilitation facility post stroke. It is estimated that 300,000-600,000 persons exhibit some form of dysphagia per year due to neurological disorders[5].

**Importance of the Knowledge to be Gained**

The research studies to be conducted under Aim 1 of this research will be the first step for determining how to optimize the proposed device characteristics for patient self-training. An early version of the vibrotactile device that was used in the small patient study at NIH was developed to provide only sensory input during self-training for comparison with an intramuscular stimulation device that was surgically implanted and studied under an FDA IDE. That study was recently completed and we found that the sensory and implanted devices had similar degrees of benefit during self-training.

We have now decided to further develop the sensory input device as it is noninvasive and much less expensive for self-training. This Phase I SBIR research will determine the optimal stimulation device characteristics before using the device in Phase II studies for eliciting swallowing during self-training in patients with oropharyngeal dysphagia post stroke.

We have reviewed the FDA requirements for our device and it may qualify as a *"Therapeutic massagers and vibrators 890.5975" under "Physical medicine devices" which are Class I 510(k) exempt devices.* The IRBs that approved an ongoing study in healthy volunteers did not consider that an IDE was needed for use of this device.

This device is undergoing development; the results of this Phase I trial will be the basis for the selection of the motor type(s), holder design, strap, frequency, mode and duration of vibration. The engineers involved in the project will be developing the device to be used for Phase II using the results from this Phase I study.

A related vibrotactile device was included as the control device in a small Phase II study evaluating the use of an intramuscular implant device for swallowing retraining between 2005 and 2009 (IDE G060153). The vibrotactile device had comparable outcomes to the implant after 12 months of daily use by patients with dysphagia. Four patients used a vibrotactile device daily for swallowing retraining for a year without adverse events.

We will submit the protocol and human subjects consent submitted to the IRBs to the FDA for this study for use in post-stroke humans with dysphagia and await their decision regarding the need for an IDE or whether the device is *Class I 510(k)* exempt.

**Data Safety and Monitoring Plan**

Data integrity will be assured by using the LabTrack electronic notebook system in Dr. Ludlow's lab which is on a secure backup server. This system meets FDA standards for data monitoring. Case Report Forms (CRF) will be setup with templates requiring entry of all essential data elements on each participant such as inclusion/exclusion criteria, consent records and records of visits, telephone contacts, and correspondence tracking each participant's involvement in the research. The LabTrack system tracks all entries, the date and the identity and any data changes by user ID. All measures will be entered into data files on the Laboratory server by participant ID no.. The PI and speech pathologist will conduct monthly quality assurance reviews of the CRFs and data files.

The outcome measures of participants' preferences will include their swallowing frequency during 10 minute periods containing short epochs of vibration to the neck area, swallowing onset times after stimulation onset and participant visual analogue scale ratings of their perceived urge to swallow during stimulation. Each of these data points will be measured from digitized Chart recordings and entered into data files by participant number in Labtrack and Excel.

Data Safety Monitoring:

During each hourly visit with a participant, we will be testing for the accumulation of secretions in the upper airway by asking participants to phonate during breaks between devices every 10-12 minutes. If a participant's voice quality is judged by the speech pathologist to have a wet gurgly quality, we will instruct the participant to regurgitate into the oral cavity and then swipe suction the mouth. The CRF will include records of phonation testing at each break, the speech pathologist's rating of the phonation and a record of whether oral suctioning was indicated and applied. All adverse events will be recorded during a test session in the CRF on encrypted Laptops connected by VPN to the LabTrack system on a server in Dr. Ludlow's laboratory. Participants' status at the end of each test session will be recorded in the CRF in LabTrack.

Participants or their caregivers will be contacted within 2 days following a test session to record their status and any difficulties following testing. The findings will be recorded in CRFs in LabTrack. All participants in the project will be asked to take their body temperature daily and to contact the PI or speech pathologist if their temperature is elevated for 3 days in sequence while participating in the project. If a participant has had an elevated temperature for 3 days in sequence they will be scheduled

to see the medical officer for the study, a Dr. Ganesh Kini, who is Medical Director of the Hospital Division at Rockingham Memorial Hospital, who will evaluate the patient.

Records of adverse events (AE) will be evaluated by the medical officer, Dr. Kini, the Study Team and the JMU and RMH IRBs for participants in the protocol and submitted to the safety officer at NIDCD on a quarterly basis. Serious adverse events (SAE) will be evaluated by Dr. Kini and reported to the IRBs at JMU and RMH and the NIDCD Safety Officer within 10 days of their occurrence.

The IRBs will evaluate the reports of AEs/SAEs to determine if use of the device shows increased risk of aspiration pneumonia and other problems indicating that use of the device produces “more than minimal“ risk.

**ClincalTrials.gov requirements**

This is a Phase I safety intervention trial assessing participants’ preferences on various device characteristics. None of the participants will be using any of the devices for self-training or dysphagia therapy in this trial. As this study is not a treatment trial, participants may continue their usual regimen of dysphagia therapy while participating in the study.

All participants will be monitored for AE/SAEs while participating in the study; it is expected that participants will undergo 3 or more visits of 1 hour each to provide feedback on the devices to the investigators over a 1-2 month period. On completion of the experiments a participant will be discharged from the study.

**Human Subjects Protect ion for Aim 2: Identifying Delivery Points for Introducing Patients to Swallowing Self-training to be conducted by Passy Muir, Inc.**

We will apply to the JMU IRB to determine if the research to be conducted for Aim 2 qualifies under Exemption 2 as exempt from the DHHS human subjects regulations the DHHS regulations as it only involves survey and interview procedures that do not involve (i) information obtained that is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

References

**1.** Robbins J, Coyle J, Rosenbek J, Roecker E, Wood J. Differentiation of normal and abnormal airway protection during swallowing using the penetration-aspiration scale. *Dysphagia.* Fall 1999;14(4):228-232.

**2.** Carnaby-Mann G, Lenius K. The bedside examination in dysphagia. *Phys Med Rehabil Clin N Am.* Nov 2008;19(4):747-768, viii.

**3.** Gonzalez-Fernandez M, Sein MT, Palmer JB. Clinical experience using the mann assessment of swallowing ability for identification of patients at risk for aspiration in a mixed-disease population. *Am J Speech Lang Pathol.* Nov 2011;20(4):331-336.

**4.** Langmore SE. *Endoscopic evaluation and treatment of swallowing disorders*. New York: Thieme; 2001.

**5.** Center EE-BP. Diagnosis and Treatment of Swallowing Disorders (Dysphagia) in Acute-Care Stroke Patients. *Evidence Report/Technology Assessment No. 8.* Vol AHCPR Publication No. 99-E024. Rockville, MD: Agency for Health Care Policy and Research; 1999.

Where will research be conducted? (Be specific; if research is being conducted off of JMU's campus a site letter of permission will be needed.)

Rockingham Memorial Hospital in the JMU-RMH Voice and swallowing Service

Will deception be used? If yes, provide the rationale for the deception:

no

What is the time frame of the study? (List the dates you plan on collecting data. This cannot be more than a year, and you cannot start conducting research until you get IRB approval.)

September 1, 2012

**Data Analysis**

What methodology will be taken to ensure the confidentiality of the data (i.e., how and where data will be stored/secured, how data will be analyzed, who will have access to data, and what will happen to data after the study is completed?)

**Reporting Procedures**

Professionals in dysphagia

Data Publication: Aim 1 will be published.

Aim 1 Offered to have publications sent to them.

**Experience of the Researcher (and advisor, *if student)*:**

Dr. Ludlow has conducted clinical research for over 35 years.

**The Passy Muir Swallowing Self Training Device to Enhance Recovery Post Stroke**
Consent to Participate in Research

Identification of Investigators

You are being asked to participate in a research study conducted by Dr. Christy Ludlow (Primary Investigator) from James Madison University, Department of Communication Sciences and Disorders. You will likely be seen at the JMU-RMH Voice and Swallowing Services office at RMH during this study. The JMU-RMH Voice and Swallowing Services is a collaborative project that includes both JMU and RMH. Dr. Ludlow is an inventor on the devices that will be tested as part of this research and could possibly benefit financially if the device becomes marketable.

Dr. Ludlow receives her salary from James Madison University; The Passy Muir, Inc., reimburses James Madison University for a portion of her salary that is equivalent to the time she spends on research using funds received from the National Institutes of Health as part of a small business innovative research grant.

Purpose of the Study

The purpose of this study is to learn whether or not using noninvasive and non-painful vibratory stimuli (like a cell phone) on the neck will change peoples' swallowing. The findings of the study will contribute to our overall understanding of swallowing and could help people with swallowing disorders in the future, but the study does not provide a new treatment for you.

Background

Safe swallowing requires the ability to control when you swallow and to protect your airway. A chronic swallowing disorder (dysphagia) can be life threatening, as it can place patients at risk for aspiration of liquids and/or solids into the trachea. Repeated aspiration of substances into the lungs can result in pneumonia. We want to see whether certain types of vibratory stimuli might be used to help people to swallow who have had a stroke and have a swallowing disorder.

Study Population

Up to 50 persons who have had at least one stroke and have a swallowing disorder.

Inclusion Criteria

You may be eligible for this research study if:

- You are 20 years old or older
- You are in stable medical condition
- You have had at least one stroke
- You have a swallowing disorder based on the review of an examination of your swallowing using videofluoroscopy. If you have not had such an examination of your swallowing in the last year and have previously had a swallowing disorder after a stroke we can arrange for you to have another videofluoroscopy that will be paid for by the research to assess your current swallowing status. We can provide you with the results of this testing if you request it.
- You will need to take a short pen and pencil test to assess your memory and cognitive skills to participate in the study. We can provide you with the results of this testing if you request it.

- We will be asking you some questions about your ability to eat food and swallow liquids. This questionnaire will assess whether you are at risk of having food enter your airway during swallowing. We can provide you with the results of this testing if you request it.

Exclusion Criteria

Exclusionary criteria by participant report:

- History of past brain injury, epilepsy, or neurological disorders (excluding stroke)
- Previous neck injury
- Psychiatric problems
- Speech problems
- Dementia, agitation, or a decreased level of alertness
- Diagnosis of progressive neurodegenerative disorders, such as dementia, Parkinson's Disease, multiple sclerosis, peripheral neuropathy, and amyotrophic lateral sclerosis

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. If you decide to participate in this study, you will be asked to participate in one or more studies (described below as Experiments, 1,2, 3 and 4) that we are conducting on different types of devices that we are assessing for future use with patients who have swallowing disorders.

To measure the effects of each vibrator, we will attach a small vibrator to the outside of your throat with a band to hold it in place. We will turn on a vibrator for different time periods such as 3 to 10 seconds, and then turn it off for between 15 to -40 seconds for up to 32 times. This may occur for up to 20 minutes at a time with short 2 minute rest period between testing different vibrators. Thus, the total time for one condition may be just over 10 minutes. These sessions will test the following.

**Experiment 1**: to identify an optimal speed of vibration

4 Vibrator Frequencies between 30 and 150 vibrations per second (30, 70, 110, and 150) and some combined vibrators will be tested in one session. This will require one hour and may be divided between different testing times if it takes more than 1 hour of testing time.

**Experiment 2**: to determine optimal pulsing rate

We will compare a pulsed vibrator and a continuous vibrator using one of the vibrators from Experiment 1. This should require less than 30 minutes of testing at a time.

**Experiment 3**: to determine vibratory pressure settings and relationship with neck fat

We will use a small balloon placed between the neck band and your neck to determine the effect of different pressure settings between the neckband and the neck which might increase the effect of the vibration using one of the vibrators we used in Experiment 1. We will also measure the thickness of the skin overlying your neck with a caliper that has 2 arms. This should require less than 30 minutes of testing at a time.

**Experiment 4**: To determine optimal automatic cycling rate:

We will compare different times of vibratory stimulation to see which duration is needed for you to initiate swallowing: between 3, 5, 7 and 9 seconds. Each trial will be approximately 10 minutes, requiring about 1 hour of testing time.

These experiments may be run on different days with you returning each day for three or more different visits.

For each experiment, we will attach a small non-invasive sensor to the outside of your neck with tape (about the size of a pea) to record when you swallow. We will also wrap bands around your rib cage and abdomen to measure your breathing. In some experiments you may have a tube placed on your tongue to record when you swallow.

You will feel shaking to the throat when a vibrator is turned on, but this will not be painful or uncomfortable. There will be periods when the vibrator is on and when it is off. Your saliva maybe suctioned if necessary. The suctioning would be done by a licensed speech pathologist.

We will also ask you to say the vowel "eee" for about 10 seconds, two times with a vibrator turned on and two times without it turned on. This will tell us whether or not the vibration is reaching your voice box.

Time Required

Participation in this study will require approximately 3 hours total from consenting to and participating in the experiments. Some of the experiments may be combined, but we expect that to complete the entire groups of studies approximately 3-5 one hour visits will be required, but more can be scheduled as needed.

Risks, Inconveniences and Discomforts

We will be measuring the frequency that you swallow your saliva during some of these studies. If you have difficulty swallowing you may find it difficult to swallow your saliva we may ask you to clear your throat and bring the saliva to your mouth so that we can suction it for you. We will test for increased saliva every 10 -12 minutes during the study. If you normally have difficulty swallowing your saliva, please let us know and we will give you some advice on how to manage this.

Many people who have swallowing problems are at a higher risk of developing pneumonia because of their swallowing problems. For that reason, while you are participating in this study we want you to take your temperature at the same time of day each day. If your temperature is elevated from your normal levels by more than 2 degrees for 3 days straight you must call us so we can arrange for someone to see you in the next couple of days to see if you have a medical problem.

We will contact you within 2 days after each test session to see if you are doing well. Please return our calls so that we can assure ourselves of your wellbeing.

*Vibrotactile Stimulation*

This is a non-invasive form of stimulation which carries no known risks. You will feel a vibration on your throat with the throat stimulator.

*Movement transducer device and Respitrace and video recording*

These are non-invasive and carry no known risks. The movement transducer device will be attached to the neck with tape which could cause brief skin irritation after removal. The Respitrace bands will be wrapped around your rib cage and abdomen during the experiment but should not cause any discomfort. A small tube will sit on the front part of your tongue and will be held in place with tape at the chin/side of mouth. This tape could cause brief skin

irritation after removal. A video recorder will record each session for later analysis and data verification. All records, including video recordings, will be kept for 2 years on an encrypted computer and the secure server and then destroyed.

Benefits

There are no direct benefits to you from participating in this research. This is not a treatment study and you should continue any treatment or regimen that you are now following for management of your swallowing disorder. The results of this stimulation study will likely yield generalizable knowledge which might benefit others with dysphagia in the future.

Confidentiality

Your participation in this study is entirely confidential. All personally identifiable data will be kept in a locked and secure location that can only be accessed by authorized investigators. The results of this project will be coded in such a way that your identity will not be attached to the final form of this study. Your identity will be disassociated from your data and you will be assigned a participant number. The researchers retain the right to use and publish non-identifiable data. The overall results of this research may be presented at professional conferences. You may sign a release form to obtain your results from this study and to allow use of your non-identifiable data for educational purposes here at JMU.

Compensation

You will be compensated $20.00 for every visit to the JMU/RMH Voice and Swallow Service for experimental research sessions while participating in this research study. For those patients without transportation to allow them to travel to the Rockingham Memorial Hospital we can offer to reimburse your transportation costs.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without it affecting your current treatment or access to care for your swallowing disorder. The investigator can remove you from the study at any time if continuation is not in your best medical interest or if you are unable to follow the study requirements.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

Laboratory of Neural Bases of Communication and Swallowing, Dr. Christy Ludlow
Communication Sciences and Disorders
James Madison University
Lab phone: (540) 568 - 5059
Office Telephone: (540) 568-3876
ludlowcx@jmu.edu

Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
cocklede@jmu.edu

Dr. Stewart Pollock
Chair, Institutional Review Board
RMH Healthcare
540-689-1000

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 20 years of age.

_____
Name of Participant (Printed)

_____ _____
Name of Participant (Signed) Date

_____ _____
Name of Researcher (Signed) Date

_____ _____
Name of Witness (Signed) Date

## Medical History

Name: _____ Date of Birth:_____
Age:_____

Phone:_____
_____
(home) (cell) (work)
Emergency Contact:
_____Relationship:_____Phone:_____
Do you have any history of:
**Voice disorders** (including laryngitis, loss of voice)? YES NO
If YES please list:_____
Did you receive medical attention? ___ What was done? _____
**Communication disorders?** YES NO
(Ex: Childhood speech or language problems)
if YES please list:_____
**Brain Injury**? YES NO
(Ex: Car accident, sports injury)
If YES please list:_____
How many? _____Were you hospitalized?_____
**Diseases/disorders**? YES NO
(Ex: Parkinsons Disease, Lyme Disease, Multiple Sclerosis, Tumor, etc.)
If YES please list:_____
**Stroke or Transient Ischemic Attacks** (mild stroke)**?** YES NO
If YES please list:_____
**Heart disease or heart attacks**? YES NO
If YES please list:_____

Do you currently have:
**Any diseases or disorders**? YES NO
If YES please list:_____
**Allergies**? YES NO
If YES please list:_____

**Any additional relevant medical information**?
_____

# Release for Participant to Obtain Research Information

I wish to receive my personal results from this study. I give permission for the investigators of the Voice and Swallowing Service to release to me my personal data for my personal records.

I wish to obtain my data electronically via email.

☐ My email address is _____

☐ I wish to obtain my data via US mail.

My permanent address is _____

_____

_____

Name (Printed) Date

_____

Name (Signed) Date

I **do not** wish to receive my personal results from this study. I **do not** give permission for the investigators of the Voice and Swallowing Service to release me my personal data for my personal records.

_____

Name (Printed) Date

_____

Name (Signed) Date

# Release of Data for Educational Purposes

I give permission for the investigators of the Voice and Swallowing Service to use my individual data for educational purposes at James Madison University and professional conferences (Your data will NOT reveal any personally identifying information). Examples of such usages would include: graphs of your brain responses to different types of stimulation where you are only identified by a participant number or charts of your responses only identifying you by a participant number.

_____
Name (Printed) Date

_____
Name (Signed) Date

I **do not** give permission for the investigators of the Voice and Swallowing Service to use my individual data for educational purposes at James Madison University and professional conferences

_____
Name (Printed) Date

_____
Name (Signed) Date

# Permission for Future Contact Release Form

I, _____, have been informed and understand that _____ in the Voice and Swallowing Service and James Madison University is conducting a research study for the advancement of the field of speech-language pathology.

Please choose from the following:

☐ I give _____ (investigators) permission for future contact. I wish to receive a copy of the research manuscript that will be submitted for publication.

☐ I am _____ (investigators) permission for future contact that may include thank you letters and advertisements for future studies. You may contact me via (Check any that apply):

☐ Email address: _____

☐ Mail to home address: _____

_____

☐ Telephone number: _____

_____
Name (Printed) Date

_____
Name (Signed) Date

☐ I **do not** give _____ (investigators) permission for future contact. I **do not** wish to receive thank you letters, advertisements for future studies, or a copy of the research manuscript that will be submitted for publication.

_____
Name (Printed) Date

_____
Name (Signed) Date