Efficacy of a Semi-occluded Mask in the Treatment of Patients With Voice Disorder

NCT03410797

February 11, 2020

PittPRO | Pitt Protocol Review Online

Date: Thursday, September 24, 2020 10:09:02 AM Print Close

View: Pitt SF: Basic Study Information 8.2

Basic Study Information

1. * **Title of study:**
   Efficacy of a variably-occluded facemask in voice therapy

2. * **Short title:**
   Efficacy of a variably-occluded facemask in voice therapy

3. * **Brief description:**
   To determine initial efficacy of a semi-occluded facemask on voice outcomes in patients with muscle tension dysphonia (MTD), lesions, and atrophy. We hypothesize that patients will demonstrate an improvement in acoustic, aerodynamic outcomes, and voice handicap index scores following therapy.

4. * **What kind of study is this?**
   Single-site study

5. * **Will an external IRB act as the IRB of record for this study?**
   ○ Yes ◉ **No**

6. * **Local principal investigator:**
   Jackie Gartner-Schmidt
   * **Is this your first submission, as PI, to the Pitt IRB?**
   ○ Yes ○ No

7. * **Does the local principal investigator have a financial interest related to this research?**
   ○ Yes ◉ **No**

8. **Attach the protocol:**
   - Sponsor/Multicenter/Investigator-initiated protocol
   - Coordinating Center supplement
   - Emergency Use Consent/ Protocol/ FDA Form 3926
   - Exempt Application form

   Document Category Date Modified Document History
   There are no items to display

View: Pitt SF: Funding Sources (not integrated with Grants)

Funding Sources

1. * **Indicate all sources of support:**
   Internal funding

2. * **Provide the source of your Internal funding:**

View: Pitt SF: Study Team Members

Study Team Members

1. * **Identify each person involved in the design, conduct, or reporting of the research (includes PI):**

Name	Roles	Department/School	Affiliation	Involved in Consent	Qualifications
Jackie Gartner-Schmidt	Principal Investigator	U of Pgh | School of Medicine | Otolaryngology	Pitt faculty	yes	Dr. Gartner-Schmidt, PhD is the Co-director of the UPMC Voice Center and Professor, Department of Otolaryngology at the University of Pittsburgh Scho... view all
Christine Harrison	Primary Study Coordinator	U of Pgh | School of Medicine | Otolaryngology Research	Pitt staff	no	

2. **External team member information: (Address all study team members in item 1. above and leave this section blank)**

Name	Description
There are no items to display	

3. **Have you,** Jackie Gartner-Schmidt**, verified that all members of the research team have the appropriate expertise, credentials, training, and if applicable, child clearances and/or hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB application?**

* ◉ **Yes** ○ No

View: Pitt SF: Study Scope 8.1

Study Scope

Check all that apply

1. * **Will this study actively recruit any of the following populations?**
   - ☐ Adults with impaired decision-making capacity
   - ☐ Children (under the applicable law of the jurisdiction in which the research will be conducted (<18 years for PA))
   - ☐ Children who are Wards of the State
   - ☐ Employees of the University of Pittsburgh/UPMC
   - ☐ Medical Students of University of Pittsburgh as primary research group
   - ☐ Students of the University of Pittsburgh
   - ☐ Neonates of uncertain viability
   - ☐ Non-viable neonates
   - ☐ Non-English speakers
   - ☐ Nursing home patients in the state of Pennsylvania
   - ☐ Pregnant women
   - ☐ Prisoners
   - ☑ N/A

2. * **Will any Waivers be requested?**
   - ☐ Waiver/Alteration of Consent
   - ☐ Waiver to Document Consent
   - ☐ Waiver/Alteration of HIPAA
   - ☐ Exception from consent for emergency research
   - ☑ N/A

3. * **Will this study involve any of the following?**
   - ☐ Specimens
   - ☐ Honest Broker to provide data/specimens
   - ☐ Return of Results to Subjects or Others
   - ☐ Fetal tissue
   - ☑ N/A

4. * **Will Protected Health Information be collected?**
   - ☐ Pitt medical records
   - ☑ UPMC medical records
   - ☐ Other Institutions' medical records
   - ☐ N/A

5. * **Other Requests?**
   - ☐ Deception (if not Exempt, also requires Waiver/Alteration of Consent)
   - ☐ Emergency Use / Single Patient Expanded Access (using FDA Form 3926)

- ☐ Placebo Arm
- ☐ Withdraw from usual care
- ☑ N/A

6. * **Determining Scientific Review:**
Department Scientific Review (DOD requires departmental review)

*** Choose the appropriate organization to conduct the scientific review:**
U of Pgh | School of Medicine | Otolaryngology

7. * **Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?**
○ Yes ● **No**

Review the HRPO policy, if participating in research at the VA Pittsburgh Healthcare System or using funding from the VA

8. * **Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?**
○ Yes ● **No**

9. * **Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?**
● **Yes** ○ No

10. * **Is this application being submitted to convert an approved study from OSIRIS to PittPRO?** (Tip Sheet)

● **Yes** ○ No

Download the OSIRIS Transition Continuing Review form, complete and upload below. If you need to attach any additional documents (e.g., data and safety monitoring reports), upload in the Local Supporting Documents page and note the Renewal on the form. ***Exempt*** *submissions in OSIRIS also need to move into PittPRO if they remain ongoing. These will not be considered transitions but new studies. Therefore, Study Scope #10 will be answered as "No." Once the new exempt determination has been issued, the OSIRIS application can be closed. Any exempt submission remaining in OSIRIS by the end of August 2020 will be closed by our office. Please use the "Add Comment" to provide the OSIRIS study number.*

OSIRIS Transition Continuing Review form:
OSIRIS Renewal and Conversion(0.01)

*** OSIRIS ID**
PRO17100675

11. * **Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after reviewing this** HUSC guidance**, does your research protocol require HUSC review? (If yes, upload the** HUSC form **in the Local Supporting Documents section). If you are unsure of review**

requirement, select yes.

○ Yes ◉ **No**

View: Pitt SF: Research Sites

Research Sites

1. **Choose all sites that apply:**
   UPMC

   *** Select the UPMC sites where research will be conducted:**
   East
   Mercy
   Passavant
   Other UPMC Site- Specify below:

   List the Other UPMC sites:
   UPMC Bethel Park

2. **Describe the availability of resources and the adequacy of the facilities to conduct this study:**
   * The UPMC Voice Center has the appropriate space and personnel to study the population indicated in this protocol. The subjects are individuals that are typically seen and evaluated by the clinicians involved in this project.

View: Pitt SF: Devices

Devices

1. *** List each device in the study that will be evaluated for safety or effectiveness:**

	Device	Purpose	Type	Attachments
View	Semi occluded Mask	This mask is being used as an additional aid in voice therapy. Subjects are being asked to speak into the mask which is thought to enhance voice therapy exercises. The semi-occluded face mask qualifies as a non-significant risk device in that: 1. It is not an implant; 2. It is not used in supporting or sustaining human life; 3. It does not aid in curing, mitigating, or treating disease; 4. It does not present a potential for serious risk to the health, safety, or welfare of the subject.	Exempt from IDE requirements	

2. **If applicable, identify each investigational device exemption (IDE) number:**

IDE Number	IDE Holder	Other Holder
There are no items to display		

3. **Attach files:** (attachments may include justification of risk determination, FDA correspondence and if the holder of the IDE is a University of Pittsburgh based, sponsor-investigator, attach both the FDA acknowledgement letter and approval letter)

Document	Category	Date Modified	Document History
There are no items to display			

4. *** Describe your plan to manage devices so that they will be used only on subjects and be used only by authorized investigators:**

Semi occluded facemasks will only be used by trained speech language pathologists who are participating in this research. The customized grommets that occlude the end of the mask were specifically made for this research study and are not available elsewhere.

View: Pitt SF: Local Site Documents

Click **Continue** as this page was intentionally left blank.

View: Pitt SF: Recruitment Methods

Recruitment Methods

*** Will you be recruiting individuals for participation in this study?**

● **Yes** ○ No

1. *** Describe who will be recruiting individuals for participation for this study:**
   Study team members also involved in clinical care.

2. *** Select all methods to be used for recruitment:**
   Directly approaching potential subjects (in-person)

3. *** Provide details on your recruitment methods:**
   Individuals will be identified during the course of usual clinical care of patients at the University of Pittsburgh Voice Center. As potential subjects are being clinically evaluated in the University of Pittsburgh Voice Center, they will encounter at least one member of the research team who will be able to determine eligibility through the clinical review of medical records associated with their visit. Once verification of eligibility is obtained, potential subjects will be approached by a member of the research team to review the informed consent document. Any and all questions will be addressed during this time.

4. *** Describe all compensation/incentives offered to participants and timing of these offers:**
   Participants will be paid $100 in total for completion of the 4 voice therapy sessions and follow-up session. The $100 payment will be made after the completion of the 5 visits (4 therapy and 1 follow up). There will be no partial payment. Payment will be managed with a reloadable debit card.

   Participants will be paid when they present for the follow-up visit after completing 4 voice therapy sessions.

5. **Recruitment materials:** (attach all material to be seen or heard by subjects, including advertisements and scripts)

Document	Category	Date Modified	Document History
There are no items to display			

View: Pitt SF: Study Aims

Study Aims

1. *** Describe the purpose, specific aims, or objectives and state the hypotheses to be tested:**
   To determine the efficacy of a semi-occluded mask in the treatment of patients with voice disorders

   To determine initial efficacy of a semi-occluded facemask on voice outcomes in patients with MTD, lesions, and atrophy. We hypothesize that patients will demonstrate an improvement in acoustic, aerodynamic outcomes, and voice handicap index scores following therapy.

2. *** Describe the relevant prior experience and gaps in current knowledge including preliminary data. Provide for the scientific or scholarly background for, rationale for, and significance of the research based on existing literature and how it will add to existing knowledge:**
   Current Semi Occluded Voice Therapy (SOVT) therapies limit the type of vocalizations that can be produced to single vowels, which does not promote learning of the healthy voice behavior in connected speech or generalization to conversation. However, recent preliminary results using a semi-occluded mask indicate that the use of certain mask port diameters may allow for natural speech production while increasing supraglottal pressure and impedance, and thereby result in elicitation of voice with increased efficiency. In addition, the use of a semi-occluded mask provides the possibility for a better transition from phonating single phonemes in therapy to training the target therapy techniques in connected speech.

   A healthy voice is essential for communicative activities of daily living. Approximately 28 million workers in the U.S. experience daily voice problems, which can impair quality of life and work performance. People of all ages, genders, and social statuses suffer from voice problems.4 People with voice problems experience worse emotional, physical, and functional impairments than people without voice problems and those with chronic diseases such as sinusitis, angina, and back pain. Voice problems represent a substantial economic cost due to accumulation of short-term disability payments and lost wages.24

   Treatment of voice disorders varies but often involves voice therapy and/or surgical intervention. Voice therapy, a non-invasive behavioral treatment for voice disorders, helps patients develop beneficial voice habits, prevents recurrence of voice disorders, and facilitates long-lasting vocal improvement. Many voice therapy techniques involve a semi-occluded vocal tract (SOVT). SOVT treatment is often characterized by sustained (straw phonation, voiced fricatives, nasals), oral oscillatory (lip buzzes, tongue trills, raspberries) or transitory phonation (plosives and glides). Straw phonation therapy, one of the most utilized SOVT methods, was first proposed in 1904 and involved phonating at different pitches into small glass tubes with varying diameters and lengths providing simultaneous semi-occlusion and extension of the vocal tract. Voice therapy exercises involving voice production with a semi-occluded and sometimes lengthened vocal tract have demonstrated

improved vocal efficiency and loudness, reduced mechanical trauma to the vocal fold mucosa, and improved source-filter interaction.

Our group recently developed a semi-occluded facemask for use in patients with and without voice disorders. Recent preliminary results using this semi-occluded facemask indicated that the use of a certain mask port diameters may elicit voice with increased efficiency. A study of 5 participants without voice disorders revealed that a mask occlusion diameter of 6.4 and 3.2 mm resulted in improved vocal efficiency. A study of the immediate effects of a semi-occluded facemask in 20 patients with voice disorders revealed that occlusions diameters of 9.6, 6.4, and 3.2 mm all resulted in significant improvements in acoustic and aerodynamic voice outcomes.

The current study aims to expand upon these past studies by investigating the efficacy of use of a semi-occluded facemask in the treatment of patients with voice disorders.

View: Pitt SF: Study Design

Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
   30

2. **Describe and explain the study design:**
   Prospective, experimental

3. **Describe the primary and secondary study endpoints:**

4. **Provide a description of the following study timelines:**

   Duration of an individual subject's active participation:
   Approximately 6 weeks
   Duration anticipated to enroll all subjects:
   12-18 months
   Estimated date for the investigator to complete this study (complete primary analyses):
   12/31/2019

5. **List the inclusion criteria:**
   males and females
   age 18-60 years old
   diagnosed by a multi-disciplinary team consisting of laryngologist and speech-language pathologist with muscle tension dysphonia (MTD) or vocal fold lesions deemed amenable to voice therapy (i.e. not surgical candidates)

6. **List the exclusion criteria:**
   Age 61 or older (excluded due to differences in vocal fold tissue structure changes in this age and older)
   Under 18 years of age
   Current smoker (greater than 5 cigarettes/week)

7. **Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?**
   ◉ **Yes** ○ No
   * **Identify the subgroups and provide a justification:**
   Our clinic and therefore voice therapy approaches are for adult populations. Further, the developing larynx of children and adolescents is different from the adult larynx. Therefore, it is not always appropriate to compare treatments and outcomes between pediatric and adult voice disordered populations.

8. **Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required**

for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):

Due to the pilot nature of the current study, we will use convenience sampling. Our clinic evaluates approximately 30 new patients each week. Behavioral voice disorders such as those included in the current research are approximately 60% of all new patient visits. Therefore, we do not anticipate difficulty recruiting our target N of 20 for this pilot investigation. A paired t-test will be used to assess whether VHI-10 improved significantly from baseline.

View: Pitt SF: Research Activities

Research Activities

1. *** Provide a detailed description of all research activities (including screening and follow-up procedures) that will be performed for the purpose of this research study. This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.**

Participants will be recruited from the University of Pittsburgh Voice Center. Participants diagnosed with a voice disorder (including primary MTD, lesions, and atrophy) by a board certified speech language pathologist (SLP) will be the target population for this study.

Participants will age 18 and older and must state willingness to attend 4 sessions of voice therapy (standard of care for voice therapy for voice disorders) and attend a one-week follow-up research testing visit.

Participants will be assigned to a voice therapist (SLP) and scheduled for 4 sessions.
Patients will be given a facemask with a semi-occlusion (SOMask) for use in clinic and with a home practice program.
The therapy program is based on treatment program designed for a semi-occluded tube therapy found in the literature and conversation training therapy, a program developed by these investigators and validated at this institution (PRO15030497).

Each voice therapy session will last approximately 45 minutes and will consist of:
Review of vocal hygiene
For all exercises, instruct patient to:
• Breathe outside of mask, phonate into mask
• Abdominal breathing
• Relaxed upper body
• SOMask connected speech- topic of subject's choice
• Auditory and kinesthetic awareness of voice production
• Embedded basic training gesture
• Prosody training
• Negative practice- patient produces the "good" voice, alternating with the "bad" voice
Home program:
• 1 min of mask speech, 4x/day practice
• Record sessions on patient's smart phone for home practice
• Log sheet for homework practice

Baseline data to be collected will be extracted from the medical record.
Data collected at Baseline:
• VHI-10 (per usual clinical care)
• auditory perceptual analysis (per usual clinical care)
• Acoustic outcomes in vowels and speech- "we were away a year ago" (per usual clinical care)
• Aerodynamic outcomes (per usual clinical care)

Medical record information will be accessed to collect clinical information related to eligibility for this project, and to record voice outcome measure information (such as the VHI-10). This information will be collected by individuals involved in this research who have normal clinical access to this information or by the research coordinator who has been granted access through the Privacy Office.

All recruitment and enrollment will take place at UPMC Mercy. Voice therapy sessions will occur at Mercy, East, and Passavant and Bethel Park.

Data collected at follow-up:
• VHI-10
• auditory perceptual analysis
• Acoustic outcomes in vowels and speech- “we were away a year ago”
• Aerodynamic outcomes
• Patient perception of voice therapy questionnaire
• Exit interview about voice therapy

2. **Upload a copy of all materials used to collect data about subjects: (Attach all surveys, interview/focus group scripts, and data collection forms except for case report forms, SCID or KSADS):**

	Document	Category	Date Modified	Document History
View	Patient Perception of Voice Therapy Ziegler_2014.pdf(0.01)	Data Collection	1/16/2019	History
View	Dev and Valid of VHI-10 Rosen_et_al-2004-The_Laryngoscope.pdf(0.01)	Data Collection	1/16/2019	History

3. *** Will blood samples be obtained for research purposes?**

○ Yes ◉ **No**

View: Pitt SF: Consent Process

Consent Process

Enter N/A in response to the following questions if a Waiver of Consent is requested for all research activities or if no subjects are being enrolled.

1. *** Indicate where the consent process will take place and at what point consent will be obtained:**
   Individuals identified as being eligible during the course of their clinical care visit at the University of Pittsburgh Voice Center will be informed of their eligibility by a co-investigator on this project. If the potential subject shows interest, a member of the research team, knowledgeable of the project will review the informed consent document with them and address any questions or concerns that arise. Potential subjects will be informed that their care at the Voice Center is not dependent on participation in this research, and that all research is voluntary. Potential subjects will also be informed that they do not have to decide to participate immediately. But we ask that they make the decision prior to receiving any voice therapy sessions so as not to confound the study results.
   Ultimately, written informed consent will be obtained from the subject by a co-investigator.

2. *** Describe the steps that will be taken to minimize coercion and undue influence, including assurance that there is sufficient time for subjects to make an informed decision:**
   Individuals will be permitted to take as much time as they need to decide. The only stipulation is that they may not have any "traditional" voice therapy sessions after determination of eligibility and enrolling into the study as this will confound the results.

3. **For studies that involve multiple visits, describe the process to ensure ongoing consent:**

4. *** Steps to be taken to ensure the subjects' understanding:**
   Individuals identified as being eligible during the course of their clinical care visit at the University of Pittsburgh Voice Center will be informed of their eligibility by a co-investigator on this project. If the potential subject shows interest, a member of the research team, knowledgeable of the project will review the informed consent document with them and address any questions or concerns that arise. Potential subjects will be informed that their care at the Voice Center is not dependent on participation in this research, and that all research is voluntary. Potential subjects will also be informed that they do not have to decide to participate immediately. But we ask that they make the decision prior to receiving any voice therapy sessions so as not to confound the study results.
   Ultimately, written informed consent will be obtained from the subject by a co-investigator.

5. * **Are you requesting an exception to the IRB policy related to the informed consent process:**

● **Yes** ○ No

* **Provide a justification and describe the qualifications of the individuals who will obtain consent:**

For this project, the PI and the Co-investigators have appropriate expertise and experience to enable them to appropriately discuss the study with participants and obtain consent.

View: Pitt SF: Consent Forms

Consent Forms

1. **Consent Forms:**

	Document	Category	Date Modified	Document History
View	Facemask consent PittPRO conv 2019.docx(0.03)	Consent Form	2/8/2019	History

Refer to the following templates and instructional documents:

- Guidance - Consent Wording
- Template - Consent Document - Short Form
- HRP-090 - SOP - Informed Consent Process for Research
- HRP-091 - SOP - Written Documentation of Consent

View: Pitt SF: Medical Records

Medical Records

1. You are required to submit this study to the Research Informatics Office, Health Record Research Request (R3). Per UPMC Policy HS-RS0005, all research projects that access or involve UPMC electronic protected health information (e-PHI) must be submitted to R3, with the exception of clinical trials that are contracted through the UPMC Office of Sponsored Programs and Research Support (OSPARS).

   Complete the R3 intake form available at http://rio.pitt.edu/services. An R3 representative will conduct a review. You will be notified once your R3 review is complete or if anything further is needed.

*** Describe the protected health information that will be collected from the covered entity and/or the research derived information that will be placed into the medical records:**
Medical record information to be accessed for research purposes may include the information associated with the eligibility of subjects as well as their follow up visit information. This would include VHI-10 score, computerized voice testing as well as the clinical examination performed by the laryngologist at any time.

View: Pitt SF: Electronic Data Management

Electronic Data Management

* **Will only anonymous data be collected (**select **NO** if identifiers will be recorded **at anytime during the conduct of the study)?**

○ Yes ◉ **No**

Select all identifiers to be collected during any phase of the research including screening:

Name:	☑	**Internet Protocol (IP) Address:**	☐
E-mail address:	☑	**Web Universal Resource Locators (URLs):**	☐
Social security #:	☐	**Social security # (for Vincent payment only):**	☑
Phone/Fax #:	☑	**Full face photo images or comparable images:**	☑
Account #:	☐	**Health plan beneficiary #:**	☐
Medical record #:	☑	**Device identifiers/serial numbers:**	☐
Certificate/license #:	☐	**Vehicle identifiers/serial #/license plate #:**	☐
		Biometric identifiers, finger and voice prints:	☐

* **a: Will you be collecting any of the following location data: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.?** ○ **Yes** ◉ **No**

* **b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?** ◉ **Yes** ○ **No**

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:

d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR**)?** ○ **Yes** ○ **No**

* **e: Provide a justification for recording Social Security numbers including why it's required, where it's stored, how it's protected and who will have access:**

SS# is only being collected as part of the Vincent payment system. This information will be stored in locked file cabinets within the locked offices of the department of Otolaryngology. Only staff involved in the payment process will have access to this information.

* **For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?** ◉ **Yes** ○ **No**

* **Will the data be** HIPAA de-identified**?** ○ **Yes** ◉ **No**

* **Briefly describe your plan to store coded data separately from the identifiable data:** Electronically stored information will be de-identified and stored using study IDs. The linkage information will be stored in a separate restricted access folder behind the UPMC firewall.

2. * **Will sensitive data be collected (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?**

◉ **Yes** ○ No

3. * **Select all locations where data will be stored or accessed (including e.g.,** personal / employer laptop or desktop**):**

	Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
View	UPMC owned desktop, laptop or other device		no	no	no
View	Server: UPMC Managed Server		yes	yes	yes

4. * **Select all technologies being used to collect data or interact with subjects:**

N/A

View: Pitt SF: Data Safety and Monitoring

Data Safety and Monitoring

1. * **Describe your plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor:**
The data and safety monitoring plan for this study will involve quarterly meetings with the PI, Co-Investigators and the staff involved to discuss: the integrity and confidentiality issues, to monitor data collection and recruitment, and to ensure compliance with protocol procedures. A review of research study procedures designed to protect the privacy of the research subjects and the confidentiality of their research data will be discussed. All breaches of confidentiality will be promptly reported to the IRB as well as the Pitt HELP desk. In addition, any unauthorized access to medical record information or unanticipated problems shall be reported to the IRB. A report will be submitted during the course of the IRB renewal of the study.

2. * **Describe your plan for sharing data and/or specimens:**
This sharing will only occur once the appropriate agreements are executed if deemed appropriate by the Office of Research.
Individuals from both Emory University and Bloomsburg University may be involved in the overall conduct of this study. Information shared with Emory and Bloomsburg University will be shared in a de-identified manner.

3. **If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:**
Confidentiality will be maintained as per the usual methods in the Dept. of Otolaryngology. Any paper documentation will be maintained in locked file cabinets within the locked offices of the Department of Otolaryngology.

View: Pitt SF: Risk and Benefits

Risk and Benefits

1. *** Enter all reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to subjects' participation in the research:**

View

Research Activity	**medical record review**
Common Risks	***No Value Entered***
Infrequent Risks	***No Value Entered***
Other Risks	**rare risk of breach of confidentiality**

View

Research Activity	**wearing partially occluded mask**
Common Risks	***No Value Entered***
Infrequent Risks	***No Value Entered***
Other Risks	**-emotional discomfort/uncomfortable feeling (as stated in consent) -potential for skin irritation due to allergy or mild contact pressure**

View

Research Activity	**voice therapy session**
Common Risks	***No Value Entered***
Infrequent Risks	***No Value Entered***
Other Risks	**rare risk of worsening voice problem**

2. *** Describe the steps that will be taken to prevent or to minimize risks:**

Confidentiality will be maintained as per the usual methods in the Dept. of Otolaryngology. All electronic subject information will be stored on password protected, restricted access servers. Any paper documentation will be maintained in locked file cabinets within the locked offices of the Department of Otolaryngology.

Though uncommon, it is possible that a patient participant's voice could worsen during a voice therapy session. If this occurs, the voice therapist will give the participant the option of discontinuing voice therapy and can refer the patient back to the treating otolaryngologist for repeat vocal fold examination if so desired.

Wearing of the partially occluded mask could potentially be uncomfortable, emotionally for some individuals. The mask is not "fixed" to the individual's face, and can be removed by the subject at any time. The subject is in control of holding the mask over their nose and mouth. In the event of skin allergy/irritation, mask use may need to be discontinued.

3. **Financial risks - will the subject or insurer be charged for any research required procedures?**

○ Yes ◉ **No**

4. **Describe the steps that will be taken to protect subjects' privacy:**
All study related procedures will be performed in private rooms as is typical of the usual clinical care associated with the diagnosis and treatment of the qualifying voice disorders. Information being collected will be limited to the minimum necessary to achieve the specific aims in this study and to lay the groundwork for future research in this area.

5. **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:**
All participants will be under the clinical care of physicians in the Department of Otolaryngology. Usual clinical practice procedures will be maintained.

6. **Describe the potential benefit that individual subjects may experience from taking part in the research or indicate if there is no direct benefit. Do not include benefits to society or others:**
Subjects may actually receive direct benefit in the form of a more rapid recovery from their voice disorder than may have been received by completing more traditional voice therapy. It is our hypothesis that all subjects will benefit in this way.

7. **Do you anticipate any circumstances under which subjects might be withdrawn from the research without their consent?**
● **Yes** ○ No

* **Describe the circumstances and any procedures for orderly termination:**
It is possible that individuals may be removed from participation due to a change in their diagnosis or a change in their treatment plan is recommended.

8. **Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and data already collected:**
Depending on the circumstances, individuals may be removed from participation and directed to alternative methods of treatment if warranted.

View: Pitt SF: Conflict of Interest

Conflict of Interest

1. * **Is this an** FDA Covered Clinical Study**?**

○ Yes ◉ **No**

*Answer **YES** if it is:*

- *A study of a drug or device in humans to be submitted in a marketing application or reclassification petition that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product); or*
- *A study in which a single investigator makes a significant contribution to the demonstration of safety.*

*Do **NOT** include:*

- *phase I tolerance studies or pharmacokinetic studies;*
- *clinical pharmacology studies (unless they are critical to an efficacy determination);*
- *large open safety studies conducted at multiple sites;*
- *treatment protocols; or*
- *parallel track protocols.*

2. * **Does this study involve a Non-Significant Risk Device and you anticipate including the results as part of any type of submission to the FDA for approval of this device?**

○ Yes ◉ **No**

3. * **Is this study funded in part or whole by a PHS Agency?**

○ Yes ◉ **No**

4. * **Does any investigator involved in this study (select all that apply):**

☐ A. Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds a 5% ownership interest or a current value of $10,000?

☐ B. Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $10,000?

☐ C. Have equity in a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed?

- ☐ D. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research and for which you are receiving royalties, milestone fees, or other proceeds that have or will exceed $10,000 in any 12-month period (include payments through the University of Pittsburgh, the Veterans Administration Pittsburgh Healthcare System, UPMC, and University of Pittsburgh Physicians)?
- ☐ E. Have an officer or management position with a company that either sponsors this research or owns the technology being evaluated or developed?
- ☐ F. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
- ☑ None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

5. **Provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):**

View: Pitt SF: Ancillary Reviews

Ancillary Reviews

1. **Ancillary reviews or notifications selected below are required based on previous answers to questions. If a selection is incorrect, return to the appropriate page and adjust the answers to questions on that page:**

- ☐ Conflict of Interest (**COI**)
- ☐ Clinical and Translational Research Center (**CTRC**)
- ☑ Data Security
- ☐ Honest Broker
- ☐ UPMC Investigational Drug Service
- ☐ Pitt Medical School Review
- ☐ Pitt+Me
- ☐ Office of Investigator-Sponsored IND & IDE Support (**O3IS**)
- ☐ Radioactive Drug Research Committee (**RDRC**)(study involves the evaluation or use of procedures that emit ionizing radiation)
- ☐ ORP Business **Manager** (required for industry sponsored studies)
- ☑ Religious Directives
- ☑ Scientific Review
- ☑ Health Record Research Request (**R3**) (required if using UPMC clinical data and authorization for other UPMC data sources for research)
- ☑ UPMC Office of Sponsored Programs and Research **Support** (using UPMC facilities and/or UPMC patients during the conduct of the study)

2. **Additional ancillary reviews the PI may choose to include as needed for the research:**

- ☐ Human Stem Cell Oversight (**hSCRO**)
- ☐ Institutional Biosafety Committee (**IBC**)(study involves deliberate transfer of recombinant or synthetic nucleic acid molecules)

View: Pitt SF: Clinical Trials

Good Clinical Practice (GCP) Training

1. * **Regardless of funding source, is this study a clinical trial (**as defined by the NIH**)?**
   ◉ **Yes** ○ No

ClinicalTrials.gov Information

Visit the University of Pittsburgh Office for ClinicalTrials.gov website or contact ctgov@pitt.edu for further information.

2. * **Was this study registered, or will it be registered, on ClinicalTrials.gov?**
   ◉ **Yes** ○ No

3. * **Is the University of Pittsburgh or UPMC the Sponsor Organization for this study record?**
   ◉ **Yes** ○ No

   * **Who will be the Responsible Party for this study record?**

   Principal Investigator of this IRB application

View: Pitt SF: Supporting Documents

Supporting Documents

1. **Attach any additional supporting documents not previously uploaded. Name the documents as you want them to appear in the approval letter:**

	Document	Category	Date Modified	Document History
View	Data Safety and Monitoring Report-PittPRO conversion 2019.docx(0.01)	Other	2/8/2019	History

View: Pitt Create

Add Storage Information

1. * **Select a Storage Type:**
   UPMC owned desktop, laptop or other device

2. **Description:**

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ○ Yes ● **No**

6. * **Is anti-virus software installed and up to date on all devices and are the operating systems kept up-to-date on all devices?**
   ● **Yes** ○ No

7. **Provide additional information as needed:**

View: Pitt Create

Add Storage Information

1. * **Select a Storage Type:**
   Server: UPMC Managed Server

2. **Description:**

3. * **Will identifiable data be stored in this location?**
   ● **Yes** ○ No

4. * **Will sensitive data be stored in this location?**
   ● **Yes** ○ No

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. **Provide additional information as needed:**

View: Pitt Risk

Risk

1. * **Research Activity:**
   medical record review

2. **Common Risks:**

3. **Infrequent Risks:**

4. **Other Risks:**
   rare risk of breach of confidentiality

View: Pitt Risk

Risk

1. * **Research Activity:**
   wearing partially occluded mask

2. **Common Risks:**

3. **Infrequent Risks:**

4. **Other Risks:**
   -emotional discomfort/uncomfortable feeling (as stated in consent) -potential for skin irritation due to allergy or mild contact pressure

View: Pitt Risk

Risk

1. * **Research Activity:**
   voice therapy session

2. **Common Risks:**

3. **Infrequent Risks:**

4. **Other Risks:**
   rare risk of worsening voice problem