Consent to Participate in a Research Study
Colorado State University

TITLE OF STUDY: *Electrotactile Stimulation of Oral Tissues*

PRINCIPAL INVESTIGATOR: Leslie Stone-Roy, Ph.D., Assistant Professor, Department of Biomedical Sciences, leslie.stone-roy@colostate.edu

CO-PRINCIPAL INVESTIGATOR AND/OR NAMES OF RESEARCH TEAM:
- John Williams, Ph.D., Associate Professor, Department of Mechanical Engineering; john.d.williams@colostate.edu; 970-491-8564
-Joel Moritz, Jr. jjmoritz@rams.colostate.edu; 720-308-2657

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH? Healthy, adult, students, faculty, and employees at Colorado State University and University of Colorado are being asked to participate in this study. You might qualify if you are a healthy adult. Testing healthy adults will enable researchers to gather preliminary data to determine the feasibility of a certain hearing assistance device.

WHO IS DOING THE STUDY? The research is being conducted by John Williams, Ph.D., Leslie Stone-Roy, PhD., and CSU Engineering Student, Joel Moritz Jr.

WHAT IS THE PURPOSE OF THIS STUDY? The purpose of this study is to test the effectiveness of small patterns of electrically charged metal dots (electrodes) in contact with oral tissues, in communicating language to a person. The study could lead to development of hearing assistance devices for the hearing impaired, allowing individuals to gain or regain hearing ability.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST? The research will take place at the CSU Anatomy and Zoology building. Your time commitment will be 1.5 - 2 hours.

WHAT WILL I BE ASKED TO DO? You will be asked to:

1.Fill out a brief questionnaire,

1. Taste a small piece of treated paper
2. Apply blue food coloring to your tongue and have the stained tongue photographed
3. Take a simple hearing test to determine the range of frequencies you can perceive
4. Experience electronic stimulation of the tongue (a low-voltage tingling sensation that feels like a vibration or a carbonated beverages)
5. Communicate with the research team
6. Record your responses to questions asked of you during the experiment
7. Chew gum while surface electrodes record muscle activity in jaw

ARE THERE REASONS WHY I SHOULD NOT TAKE PART IN THIS STUDY? Persons under 18 years of age should not participate in this study, as one of the key goals of the study is to determine the level of assistance that a hearing assistance device provides to people with the type of hearing loss common in adults. Persons with any open wounds, cut or sores in their mouths or acute or chronic illnesses are asked not to participate in this study, as these can increase the risk of transmitting infections between participants and from participant to researcher. Known allergies to propylthiouracil (PROP), Methimazole, or food dye are reasons to not participate. Persons with any external or implanted electrical devices such as pace makers and vagal nerve stimulators should not participate in this study as there is a small possibility that the device being tested could electrically interfere with those medical devices. Risks could include but are not limited to; discomfort of the tongue, and excess salivation.

- It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known and potential, but unknown, risks.

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ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY? There may be no direct benefit to you associated with this research; however, the study could lead to development of hearing assistance devices for the hearing impaired, allowing individuals to gain or regain hearing ability.

DO I HAVE TO TAKE PART IN THE STUDY? Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

WHO WILL SEE THE INFORMATION THAT I GIVE? We will keep private all research records that identify you, to the extent allowed by law.

For this study, we will assign a code to your data. Your responses to the questionnaire and questions will be recorded on numbered forms and no names or identifying information will be recorded with the data. No one (not even the research team) will be able to identify that the data came from you. Only the research team will have access to your data. The only exception to this is if we are asked to share the research files for audit purposes with the CSU Institutional Review Board ethics committee, if necessary. When we write about the study to share with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH? The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury.

WHAT IF I HAVE QUESTIONS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigators: Joel Moritz Jr, jjmoritz@rams.colostate.edu or Dr. Leslie Stone-Roy, leslie.stone-roy@colostate.edu. If you have any questions about your rights as a volunteer in this research, contact CSU IRB at RICRO_IRB@mail.colostate.edu; 970-491-1553. We will give you a copy of this consent form to take with you.

WHAT ELSE DO I NEED TO KNOW?

Conflict of interest disclosure: Joel Moritz Jr. is the President of Sapien, LLC, and both Mr. Moritz and Dr. Stone-Roy are listed on the submitted patent entitled: Tongue Stimulation for Communication to a User.

Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 2 pages.

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of person providing information to participant Date

_____
Signature of Research Staff

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