RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Effects of an External Oral Irrigation Device in Patients with Dry Mouth

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SPONSOR: Voutia

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.**

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to test the effectiveness of treating dry mouth through water rehydration using this extra oral water pump/irrigation device. You are being asked to participate in this study because you have been diagnosed with dry mouth, and may meet the study entry requirements.

Dry mouth causes difficulty with chewing, swallowing, speech, and increases the risk dental cavities. It also can cause discomfort in your mouth, and a loss of general quality of life. The oral irrigation device supplies a small amount of water to your mouth through a small tube that you place in the corner of your mouth throughout the time you wear it.

What will happen if I participate?

In this study, you will be asked to do the following things:

1. Visit the dental school clinic two (2) times for study visits.
2. Wear the oral irrigation device as directed by the investigator.

3. Keep notes at home.
4. Answer survey questions during both dental visits about your dry mouth symptoms.
5. Give permission for the researchers to collect information about medications or health conditions that contribute to your dry mouth from your medical records.

Your participation in this study will last up 4-6 weeks. Approximately twenty-five (25) individuals will participate in this study.

What alternative treatments or procedures are available?

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes instructions on proper oral hygiene and current topical strategies to lessen the effects of dry mouth, like sipping water through the day and using prescription-strength fluoride toothpastes. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for dry mouth.

You will not receive the oral irrigation device without being in the study.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
• Wearing the device may cause discomfort over long periods to the corner of the mouth where placed. • Water flow may be too much or too little at time during the use of the irrigation device. • Device may become damaged, risking battery burns if left near exposed skin. • The study questionnaires ask questions that are personal in nature and may make you feel uncomfortable. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.	There is some evidence that the oral irrigation device is effective in lessening the effects of dry mouth. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study doctors learn things that may help other people in the future.

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Questionnaires may contain questions that are personal in nature. You may refuse to answer any question that makes you feel uncomfortable.

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

The oral irrigation device involves risks that are currently unknown or unforeseeable.

WHAT ARE THE COSTS?

During the course of the study, the oral irrigation device will be provided by the sponsor at no cost to you. You will not be charged for any study related procedures, such as use of the device or completion of the study surveys. However, please note that any standard-of-care clinical visit fees are still your responsibility.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third-party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

If you leave the study before the final regularly scheduled visit, you will need to return the irrigation device to us immediately. There are no foreseeable risks to stopping the use of the oral irrigation device.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the will be included in the record. This information is protected just as any of your other health records are protected. In the future, once identifiers have been removed, the information you've provided could be used for future research.

This information will be destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you through mail or email, although we expect that this will be a very rare occurrence.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires and added to your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

- ☒ Complete health record
- ☒ Diagnosis & treatment notes
- ☒ History and physical exam
- ☒ Salivary test results
- ☐ Photographs, videotapes
- ☐ Information about drug or alcohol abuse
- ☐ Information about mental health
- ☒ X-ray films / images

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor
- Data Coordinators
- Research Collaborators

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at
Dr. Susie Goolsby,
520 N. 12th Street, Lyons Building room 430c
Box 980566,
Richmond, VA 23298-0566

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Investigator: Dr. Goolsby at srgoolsby@vcu.edu, or (985)209-8116
and/or
Your student dentist:_____

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human-research/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date