INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

SaliPen Human Factors Study for OTC labeling
IRB Protocol Number 12473
Saliwell Ltd., Protocol Number 21-D-246

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

This study will have 2 parts, Phase I and Phase II. The purpose of Phase I is to see if an individual can determine if a device known as the "SaliPen" is appropriate to treat their condition by reading the outside of the package without any assistance or direction. The purpose of Phase II is to see if an individual that experiences dry mouth symptoms is able to use the "SaliPen" as instructed by reading the instructions on the inside of the package without any assistance or direction and by watching a YouTube video. This information will help determine what, if any changes should be made to the packaging and instructions to prepare the device for over-the-counter use.

SaliPen is approved for use in the USA by the Food & Drug Administration (FDA), but you must currently obtain a prescription from a medical doctor or a dental practitioner.

We are asking you if you want to be in this study because you have expressed interest in participating in our research study and you may or may not have a condition known as Dry Mouth or Xerostomia.

The study is being conducted by Principal Investigator, Dr. Susan Zunt, of the Indiana University School of Dentistry at Oral Health Research Institute. It is funded by Saliwell Ltd., who manufactures the device SaliPen.

HOW MANY PEOPLE WILL TAKE PART?

If you are participating in Phase I, you will be one of 16 participants (8 with reported dry mouth and 8 without) taking part in the study. If you are participating in Phase II, you will be one of 16 participants with reported dry mouth taking part in the study. If you have dry mouth and participate in Phase I of this study, you may also participate in Phase II.

WHAT WILL HAPPEN DURING THE STUDY?
You will be asked to attend one visit at Oral Health Research Institute. You will be asked to read this consent. The information in this form will be explained to you, and you will have the chance to ask questions before you decide if you want to be in this study.

If you are participating in Phase I, you will be asked to read the labeling on the outside of the SaliPen package. Thereafter, you will be asked to complete a questionnaire and determine if the device is appropriate for your use without any additional assistance or direction.

If you are participating in Phase II, you will be asked to read the labeling on the inside of the SaliPen package. You will also be given the opportunity to watch the referenced YouTube video on a device (computer or iPad) at the site. You will then be instructed to use the SaliPen without any additional assistance or direction. Thereafter, you will be asked to complete a questionnaire. The study dentist will perform a brief exam of your mouth at the beginning and at the end of your visit. You will have the option to keep your SaliPen device. Your visit will last approximately 45 minutes.

If you participate in both Phase I and Phase II, you will have the option of completing all procedures during the same visit.

You will not receive the results of any of these tests or procedures because they are being done only for research purposes.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
We do not expect any negative effects from participating in this study; however, you may be uncomfortable while answering the questions in the questionnaire. While completing the questionnaire, you can skip any questions that make you uncomfortable or that you do not want to answer.

If you are participating in Phase II, you may experience some discomfort and mild pulsating in the areas of the mouth that are in contact with the SaliPen device. You will be offered the option to pause and remove the device upon request. There is also a risk of infection, inflammation, and allergic reaction of the oral tissues. As a precaution, following the use of the SaliPen, we will ask you questions regarding any side effects or symptoms you may have experienced, and the study dentist will perform a brief exam of your mouth. You should tell us if you feel you are having any symptoms related to the SaliPen device. If you experience an allergic reaction, medical assistance will be offered.

Accidental loss of confidentiality of records is possible. To reduce this risk, all study records and data will be stored in locked cabinets and encrypted, and in password protected computer files that only study personnel can access. With the exception of the forms you sign (like this consent), a study number will be the only thing that identifies your records.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you. The study sponsor has agreed to pay for the direct, reasonable, and necessary costs of treatment for any injury or bad reaction that directly results from your use of the SaliPen device or any procedure required by the Protocol (only because you are in this study). The study sponsor will not pay for any costs resulting accidents that are not related to your participation in this study or from any pre-existing abnormal medical condition or an underlying disease (unless your pre-existing condition or underlying disease is made worse by your proper use of the SaliPen device or any Protocol-required procedures). However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will receive $25 cash for participating in either phase of this study. Should you participate in both phases, you will receive $50 cash. If you participate in Phase II, you will be given the option to keep the SaliPen device.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsor: **Saliwell Ltd.**
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Susan Zunt, at 317-274-5250.
In the event of an emergency, you may contact Dr. Zunt or her staff by calling the after-hours emergency answering service at (317) 278-9095. A staff member will put you in touch with one of our researchers.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you.

If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University.

Please indicate which phase of the study you would like to participate in by checking the one of the boxes below:

Please Note- Prior to making your selection you will be informed if we have met the enrollment for either phase.

☐ You do not have dry mouth and would like to participate in **Phase I**.

☐ You have dry mouth symptoms and would like to participate in **Phase I** only.

☐ You have dry mouth symptoms and would like to participate in **Phase II** only.

☐ You have dry mouth symptoms and would like to participate in both, **Phase I and Phase II**.

PARTICIPANT'S CONSENT

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name	**Date**
Participant's Signature	

Printed Name of Person Obtaining Consent	**Date**
Signature of Person Obtaining Consent	