THE UNIVERSITY OF TEXAS MEDICAL BRANCH

The University of Texas Medical Branch (UTMB Health)

More Than Minimal Risk Consent Form (In-Person Consent for Adults)

Protocol Title:	Translating Science into Tools for Return of Facial Function
IRB Number:	25.0178
Sponsor:	UTMB Speech Pathology Department
Principal Investigator:	Kathleen Kerr, MS, CCC-SLP
Version Number:	1
Version Date:	13 August 2025

Please read this entire consent form or have someone read it with you. It contains important information that can help you decide if you want to be part of the study or not. If there is anything that you do not understand, please talk to the study doctor or team to have your questions answered before signing the consent form.

IMPORTANT:

- **Taking part in this research study is voluntary. *You do not have to participate, and you may stop at any time.***
- ***If you are providing consent for someone else*, please note that in the sections that follow, the word "you" refers to the person for whom you are providing consent. For example, if you are providing consent on behalf of your child, the "you" in this document refers to your child.**
- **If you are a patient of UTMB Health, your provider *may* be an investigator in this study. If so, please understand that your doctor is interested in *both* your medical care and the conduct of this research study. You may discuss your care with another doctor who is not part of this research study *at any time*.**

KEY INFORMATION

Your Rights as a Study Participant

You are invited to take part in a research study. Your participation in this study is completely voluntary. You are not required to take part. You can choose to take part, or you can decide that you do not want to take part. If your provider has invited you to take part, you do not have to accept the invitation. Choosing not to take part will have no effect on your medical care. If you choose to participate, but change your mind at any point, you can withdraw without any penalty.

Length of Participation

Your participation in this research study will last eight (8) weeks and will include 1 visit per week for a total of 8 visits (including your initial and final assessment).

Purpose

The purpose of this study is to test a new tool developed to assist in the treatment and rehabilitation of lower facial burns and facial injuries, increase range of motion and the abilityto chew and speak, while lessening the need for surgery. This tool or set of tools is called the OraPlace.

Procedures

You will not take part in any study activities before you have gone through the entire Informed Consent process, had all your questions answered, any concerns addressed and you have signed and dated this Informed Consent document indicating that you consent to participate in this study. Pediatric subjects must have a parent or legal guardian provide consent on your behalf and who will commit to attend all study visits during the 8-week study period.

If you decide to take part in the study and you have given your consent, you will be given the option to participate in-person or electronically, via telehealth. The study procedures you would follow if you participated in-person or via telehealth are essentially the same, with a few minor differences. In either case, if you consent to participate, you will complete an initial assessment during which the Speech Pathologists will take various measurements, including pupil distance and facial measurements at rest and while completing specific facial movements. Photographs of your face will be taken at the initial visit and at each weekly visit. This is done to document your “starting point,” before any study activities have taken place. This way, by comparing your measurements after study activities to your starting point, investigators can see any changes that may have resulted.

Besides taking the starting point measurements, the Speech Pathologists will also select the appropriate orofacial splint(s) and placement location based on the initial assessment. They will also train you in the procedures you will follow as part of this study, how to select the appropriate splint(s), proper placement, and how to keep track of what you do during the trials.

Once you are comfortable and confident that you know how to use and place the tools, you will be issued a tool kit with everything you will need to perform the study procedures, including a set of splints in various sizes and shapes and the documents you will use to keep track of which splint(s) you used, placement location, date and number of minutes you used the device. You will keep this tool kit with you at home when you perform the study trials. You will perform two trials per day, every day, for 8 weeks. Each study trial will consist of selecting the appropriate splint(s), placing them according to the instructions you received, wearing them for up to one hour per session. As the trials progress, you may use different shapes and sizes of splint(s) in different locations depending on the measurements taken throughout the study.

Your measurements will be taken weekly, during your weekly study visits with the Speech Pathologist. You will meet with the Speech Pathologist either in person, at a UTMB Health clinic or your home, or via telehealth. During each visit, the Speech Pathologist will measure you in the same way you were measured during the initial study visit and assessment. Pictures will be taken of your face in 5 different facial expressions. These photographs will be stored on a

secure UTMB Health server. Using the newest measurements, the Speech Pathologist will again select the appropriate splint(s) and placement location. You will continue the same schedule, performing the same procedures each week, for a total of 8 weeks. Additionally, you will record your study trials on the charts included in your tool kit. You should record the information every day, immediately following each trial to ensure accuracy. You will email these completed charts to the investigators weekly or mail them to the investigators at the end of the study, together with the oral splints, using the postage paid envelopes provided in the tool kit.

Potential Risks

There is a minimal risk of the following:

- Discomfort from stretching of skin
- Bleeding if the facial burn or injury sites are not fully healed
- Allergic reaction to some of the materials used in creating the tool
- Uneven range of motion
- Possible tears in the burned or injured skin
- Risk of choking on the splint if it becomes separated from the safety handle, however, if properly used, the handle will not separate from the splint. This risk will be mitigated by detailed instructions on the proper use of the tool by the trained investigator before you use the device.

In addition to the minimal physical risks listed above, there is a minimal risk of unauthorized access to your confidential data and private health information. Every effort will be made to guard your information against unauthorized access. You will be assigned a subject ID number after you have consented to participate, you will only be referred to by that number throughout your participation, your private information and confidential data will be linked to the subject ID number but will not be stored with the remaining study documents, data collected from you will be kept electronically on UTMB Health password-protected computers, on a secure server, behind UTMB Health's firewall. There will be a small number of paper copy (hard copy) documents collected and maintained. Those documents will be kept in a locked cabinet in a locked office. Access to those documents will be strictly limited to IRB-approved study personnel authorized by the Principal Investigator to access them.

Alternative to Study Participation

You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- You may continue to receive treatment with your regular physician and medical team. These treatments include compression garments, surgeries, scar massage, topical treatments, among others.

Please talk to the researchers or your personal doctor about these options.

Costs Related to Participation

You will not be responsible for any research-related costs; insurance companies will not be billed. You will be provided with postage paid envelopes for mailing your weekly charts to investigators. Subjects participating in-person will have their parking validated for each visit.

You will be responsible for paying any costs related to illnesses and medical events **not associated with being in the study**.

Compensation and Medical Treatment for Research-Related Injuries

Participants will not be compensated for taking part in this study.

In case you experience any illness or injury while involved in this study, it is important that you immediately report the situation to the research team listed on this form.

Compensation for an injury resulting from your participation in this research is not available from UTMB Health.

This overview only includes *some* of the information you need before deciding whether to take part. Additional details are given in the full consent document, which can be found on the following pages. Be sure to carefully review the rest of this consent form, ask questions if you have them, ask for clarification if you need it and discuss any concerns you have with the consenting investigator before deciding about participation.

DETAILED INFORMATION

What is the purpose of this study?

Burn injuries must be treated and rehabilitation begun promptly if the patient is to regain function in the injured areas. Typically, upper and lower extremities (arms, legs) are prioritized for treatment and rehabilitation, with facial burns receiving treatment and rehabilitation as a secondary concern. Because the muscles and tissues of the face serve important functions, the neglect in, or delay of treatment and rehabilitation can have a negative impact on the patient's ability to regain related function and may detract from their quality of life. Therefore, it is critically important that the treatment and rehabilitation of facial injuries is begun promptly, along with that for the upper and lower extremities.

This study is focused on the treatment and rehabilitation of burns and other injuries to the lower region of the face. The lower facial region controls facial movement, the ability to make facial expressions, chewing, speaking and allowing for complete oral care. Burns and other injuries, scarring and contractures in this region disrupt those abilities. Current treatment and rehabilitation of lower facial burn injuries and other facial trauma involves using an oral splint to stretch the injured and scarred skin, surgery, laser therapy, silicone masks and injections. These methods have demonstrated only partial success.

This study will test a new design of oral splint, with three different shapes, in small, medium and large sizes, to better fit specific areas of the lower face. Study investigators propose that, if implemented promptly, the new design of oral splint will have a higher rate of successful rehabilitation because it can be better adapted to the unique characteristics of each patient's unique lower facial burns and other injuries.

The principal investigator and co-investigator are inventors of the oral splints and intraoral methodology being used in this study. The University of Texas Board of Regents holds the patent for both the oral splints and intraoral methodology and has licensed this technology to an outside company. Royalties may be received from sales. The oral splints used in this study are manufactured by an outside company and use food-grade silicone. You may ask Kathleen Kerr or Lori Arguello for more information about this financial interest.

A description of this clinical trial will be available on www.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.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because -

- You are between the ages of 7 and 100 years of age
- You have a facial burn or other facial injury and are now in the outpatient or chronic healing phase
- Because of your burn or other facial injury, you have limited ability to open your mouth, difficulty chewing or speaking, decreased range of motion of your mouth and/or limited facial expressions

- You meet all eligibility criteria for taking part in this study

Am I required to participate in this study?

You are not required to participate in this study. Your participation in this study is completely voluntary. You may refuse to take part at any time, without penalty or loss of benefits to which you are otherwise entitled. Refusing to participate or withdrawing from this study will not otherwise impact your medical care at UTMB Health. The alternative to participating is that you may continue to receive treatment with your regular physician and medical team. These treatments include compression garments, surgeries, scar massage, topical treatments, among others. Please talk to the researchers or your personal doctor about these options.

How long will the study last?

If you agree to take part, your participation will last for 8 weeks and will include 1 visit per week for a total of 8 visits (including your initial and final assessment).

How many people will participate in this study?

We expect 50 participants for this study.

What tests and procedures are involved in this research study?

If you decide to take part in the study and you have given your consent, you will be given the option to participate in-person or electronically, via telehealth. The study procedures you would follow if you participate in-person or via telehealth are essentially the same, with a few minor differences. Once you agree to take part in this study, and you sign this consent form, you will be asked to complete the following tests and procedures:

- You will undergo an initial assessment, during which the Speech Pathologists will take various measurements, including pupil distance and facial measurements at rest and while completing specific facial movements.
- The Speech Pathologists will select the appropriate orofacial splint(s) and placement location based on the initial assessment.
- You will receive training on how to select the appropriate splint(s), proper placement, and how to keep track of what you do during the trials.
- You will be issued a numbered tool kit with everything you will need to perform the study procedures, including a set of splints in various sizes and shapes and the documents you will use to keep track of which splint(s) you used, placement location, date and number of minutes you used the device. You will keep this tool kit with you at home when you perform the study trials.
- You will perform two trials per day, every day, for 8 weeks. Each study trial will consist of selecting the appropriate splint(s), placing them according to the instructions you received, wearing them for one hour per trial. As the trials progress, you may use different shapes and

sizes of splint(s) in different locations depending on the measurements taken throughout the study.

- Your measurements will be taken weekly, during your weekly (in-person or telehealth) study visits with the Speech Pathologist. During each visit, the Speech Pathologist will measure you in the same way you were measured during the initial study visit and assessment.
- If your study visits take place in person, one of the study investigators will take pictures of your face as you make 5 different facial expressions.
- If your study visits take place via telehealth, you or the investigators will take screenshots of your face as you make 5 different facial expressions and send those to the Speech Pathologist at the secure, encrypted email address provided with the information you will find in your tool kit.
- Using the newest measurements, the Speech Pathologist will again select the appropriate splint(s) and placement location. You will continue the same schedule, performing the same procedures each week, for a total of 8 weeks.
- Additionally, you will record your study trials on the charts included in your tool kit. You should record the information every day, immediately following each trial to ensure accuracy.
- You will email these completed charts to the investigators weekly or mail them to us at the end of the study using the postage paid envelopes provided in the tool kit. You will return the oral splints at the end of the study as well.
- Once you have performed all trials during the 8-week study period, your participation will have ended.

What are the possible risks for participating in this study?

We do not expect adverse physical effects from using these tools. However, there is a minimal risk of the following:

- Discomfort from stretching
- Bleeding if the facial burn or other facial injury sites are not fully healed
- Allergic reaction to some of the materials used in creating the tool
- Uneven range of motion
- Possible tears in the burned or injured skin
- Risk of choking on the splint if it becomes separated from the safety handle, however, if properly used, the handle will not separate from the splint. A trained study investigator approved by UTMB Health's Institutional Review Board (IRB) will give you detailed instructions on how to properly use the tool before you begin using it, to lessen the chance of these risks occurring. You should discuss these risks and complications with the research team, as well as your primary care provider.

In addition to the minimal physical risks listed above, there is a minimal risk of unauthorized access to your confidential data and private health information. Every effort will be made to guard your information against unauthorized access. You will be assigned a subject ID number after you have consented to participate, you will only be referred to by that number throughout your participation, your private information and confidential data will be linked to the subject ID number but will not be stored with the remaining study documents, data collected from you will be kept electronically on UTMB Health password-protected computers, on a secure server, behind UTMB Health's firewall. There will be a small number of paper copy (hard copy) documents collected and maintained. Those documents will be kept in a locked cabinet in a locked office. Access to those documents will be strictly limited to IRB-approved study personnel authorized by the Principal Investigator to access them.

Are there risks for withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. There is no risk for withdrawing from the study.

If I agree to take part in this research study, will I be informed of any new risks that may be found during the study?

You will be informed of any new information regarding risks that becomes available during the study that is important for your health and safety or that could cause you to change your mind about taking part in the study.

What are the potential benefits of participating in this study?

While we cannot guarantee you will benefit directly from your participation in this study, there is a possibility that you may experience some improvement in your ability to move your facial skin and muscles, in the texture and appearance of facial scars, in your ability to make different facial expressions, in speaking so that you are more easily understood, and in your ability to perform complete oral care.

While direct benefit is not certain, we hope your participation will benefit the community of patients with facial burns similar to yours, by providing very important information about the effectiveness of the study tools.

Will I be reimbursed for participating in this study?

You will not be reimbursed for participating in this study.

If I agree to take part in this research, can I be removed from the study without my consent?

You may be removed from the study without your consent or approval for any number of reasons, including the following:

- You are not able to keep appointments
- If a pediatric subject, your parent or legal guardian is not able to attend all appointments

- You are not able to complete required procedures or follow instructions
- Study investigators believe further participation in the study is no longer safe for you
- Study investigators believe other treatments may be more beneficial to you
- The study is discontinued

Will my insurance provider or I be charged for the costs of any part of this research study?

Neither you nor your insurance provider will be charged for anything done solely for this research study (i.e., the screening procedures, experimental procedures, monitoring/follow-up procedures, etc). However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility, or the responsibility of your insurance provider or governmental program.
Postage paid envelopes will be provided to you for mailing materials to the study investigators. If you elect to participate in person, your parking will be validated.

What happens if I am injured or become ill as a result of taking part in this study?

It is important that you report any illness or injury to the research team and principal investigator listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from UTMB Health.

Reminder: You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

What happens to the data collected in the study?

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not financially benefit from those efforts.

UTMB Health researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others. will do our best to protect and maintain your data and/or specimens in a safe way. One of the ways we protect data is by limiting the use of the information and the type of information that is shared, especially your personal information. This may occur through de-identifying the data, data sharing agreements and review by oversight groups within UTMB Health.

In limited circumstances, data and/or specimens may be used or shared with types of information that may be likely to identify you, such as your name, address or medical record number for future research purposes at UTMB Health, only after the research has been

reviewed and approved by the UTMB Health IRB. The IRB will review whether additional consent from you is required.

Generally, if your data and/or specimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at UTMB Health and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

How will my information be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed. To protect your privacy, the study staff will use code numbers or letters to identify your health information instead of your name, whenever possible. If the results of this study are reported in public settings like medical journals or conferences, you will not be identified.

By signing this consent form, you give us permission, called your “authorization” to collect, use, and disclose your personal health information. We have strict regulations, including Federal and State laws, designed to protect information about you. This includes information learned from the procedures described in this consent form. The research team may also collect other information from you, including your name, your address, your date of birth, and information from your medical records. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Other professionals at UTMB Health, such as your doctor(s) and the IRB, may also see your information. We make this information available to your doctors for your safety. Please inform your doctor If you think this study might affect your clinical care.

People outside of UTMB Health may also need to see and review your information for this study. UTMB Health does not allow identifiable information collected during the study to be released to people outside of UTMB Health except as required by law or otherwise stated in this consent form. Examples include government agencies, such as the Food and Drug

Administration (FDA), individuals who monitor the study for safety purposes, other location sites in the study, and companies that sponsor (help organize or pay for) the study.

We cannot do this study and cannot use and distribute your information without your authorization. You do not have to sign this form. However, if you choose not to sign it, you cannot be in the study. Your care or the benefits you receive from will not be affected if you decide not to be in the study.

You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact the principal investigator in writing.

How long does this authorization to use my information last?

When you sign this form, you agree to let us collect, produce, and share health information about you as we described in this form. Your authorization does not end.

Who can I contact with questions about this research study?

If you have any questions, concerns, or complaints before, during, or after the research study, or if you need to report a research-related injury or bad side effect, you should immediately contact

Kathleen Kerr
Office telephone: 409.772.2711

After usual business hours –
Telephone: 713.404.5601
Pager: 409.643.1395

Lori Arguello
Office telephone: 409.772.2711

The UTMB Health IRB has reviewed and approved this study. If you have any concerns, complaints, suggestions, or questions regarding your rights as a participant participating in this research study, or if you would like more information about the protection of human subjects in research, you may contact the IRB office at irb@utmb.edu.

THIS SECTION TO BE COMPLETED BY PARTICIPANT ONLY!

CONSENT TO PARTICIPATE

The purpose of this research study, procedures to be followed, risks and benefits have been explained to me. I have been given the opportunity to ask questions, and my questions have been answered to my satisfaction. I have been told who to contact if I have additional questions. By signing this form, I am confirming that I have read this consent form and voluntarily agree to participate as a subject in this study.

_____

PARTICIPANT'S PRINTED NAME

_____ _____

PARTICIPANT'S SIGNATURE **DATE OF CONSENT**

If Pediatric Participant –

_____

PARTICIPANT'S PRINTED NAME

_____ _____

PARENT, LEGAL GUARDIAN OR LEGALLY AUTHORIZED REPRESENTATIVE'S PRINTED NAME **RELATIONSHIP TO PARTICIPANT**

_____ _____

PARENT, LEGAL GUARDIAN OR LEGALLY AUTHORIZED REPRESENTATIVE'S SIGNATURE **DATE OF CONSENT**

THIS SECTION TO BE COMPLETED BY CONSENTING INVESTIGATOR ONLY!

Using language that is understandable and appropriate, I have discussed this project, and the items listed above with the participant. I have given the participant the opportunity to ask questions about the study and procedures and have answered all questions.

_____

CONSENTER'S PRINTED NAME

_____ _____

CONSENTER'S SIGNATURE **DATE & TIME OF CONSENT**