IRB Review
IRB NUMBER: 20-045-2
IRB APPROVAL DATE: 09/18/2023

UCONN HEALTH

Division of Behavioral Sciences and Community Health

TMD 3c

Statement of Informed Consent

Project Title:	**Individualized Assessment and Treatment Program for TMD: Coping as a Mechanism**
Principal Investigator:	**Mark Litt, Ph.D.**
Division/Dept.:	**Behavioral Sciences and Community Health/Psychiatry**
Institution:	**UConn Health**
Expected Length of Participation:	**13-14 months**
Funding Source:	**National Institute of Dental and Craniofacial Research**
IRB#:	**20-045-2**
Version:	**1.1 07/27/2021**

Participant Name: _____

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision to participate in this study.

This research is being done to determine if one type of treatment for chronic orofacial pain is more effective than another type. The pain problems studied include temporomandibular joint pain (TMJ) or temporomandibular dysfunction pain (TMD), among others.

Your involvement in this treatment research would entail the following:

- This initial diagnostic visit (including a panoramic x-ray and oral examination performed by a dentist) and completion of surveys. Surveys will be completed online, and may be administered via teleconference for your safety.
- Getting dental impressions taken for the purpose of fitting you with a dental splint
- 2 weeks of pretreatment monitoring using a smartphone app, 4 times per day, each day. The monitoring periods will be repeated for weeklong periods during treatment at Week 2 and Week 4, for a week after treatment is completed, and for a week at Month 3 and at Month 12 of the follow-up period
- Delivery and fitting of a dental splint by our Dental Staff at the start of treatment
- Prescription of non-steroidal anti-inflammatory drugs to be used on a schedule for a 2-week period
- 6 weekly 60-90 minute treatment visits with a pain therapist. Such visits may be conducted remotely.
- Online surveys and teleconferences every 3 months after treatment is over for the following 9 months, out to 12 months

This adds up to about 13-14 months of involvement with this study, with total possible compensation (for completing monitoring and attending study visits) of $445 over the entire study.

During the monitoring periods you will be asked to monitor your thoughts, feelings, and behaviors on your cellphone before, during, and after treatment. Each of the treatments will consist of 6 weekly visits with a pain therapist to analyze your pain problems and to find solutions to help reduce your pain and improve your functioning.

The TMD monitoring app procedures are the only procedures in this study that might be considered “experimental,” in the sense that they are not part of standard medical/clinical practice.

The most severe risk of this study is clinical deterioration (worsening of your pain problem despite treatment). The most common risks are continuation of the pain problem and loss of confidentiality. Some of the questions on the surveys may seem very personal. Risks are described in more detail later in this document, along with our efforts to minimize those risks.

The treatment provided here may help you manage your pain. While in the study your progress will be followed closely, and we will be available to help you with any problems you might have. This research may also result in information that leads to improved treatments that could help others in the future.

Before making a decision about whether to participate in this research you should know that there are other options available to you. There are other treatment providers in your area.

A more detailed description of this research follows.

Purpose of the Research

The goal of this research is to determine which of the two treatments described below is more effective for helping patients manage their orofacial pain problem. Each treatment will involve 6 individual outpatient sessions with a pain therapist, each session being about one hour (except the first, which will take longer). About 160 participants will be recruited. You are being asked to participate because you have indicated that you have a significant orofacial pain problem, such as pain in the area of the temporomandibular joint, and that you wish to seek treatment for that problem.

Two treatments are being studied:

1. Standard Conservative Treatment + Cognitive-Behavioral Treatment (STD+CBT); and
2. Standard Treatment + Individualized Assessment and Treatment Program (STD+IATP).

Both of these treatments have been used to help people manage orofacial pain problems, but there is not much research on IATP. The first treatment described below, STD+CBT, is used extensively and is effective for many people. We are testing both of these in one study.

The two treatments we are studying are as follows:

1. The first type of treatment is Standard conservative treatment plus Packaged Cognitive-Behavioral Treatment (PCBT). Standard Treatment (STD) will consist of 3 parts: Delivery of a dental splint; prescription of a soft diet; and prescription of oral non-steroidal, anti-inflammatory medications. The splint, a plastic mouthpiece that fits snugly over your upper teeth, is used to change the oral habits of patients with respect to clenching and tooth grinding (if present), and to provide a sufficient respite from pain to allow more adaptive oral habits to emerge. Patients will receive the intraoral splint during the first treatment visit, 1-2 weeks after the baseline visit, with instructions to keep it in place continuously (except for eating) if possible for the succeeding 4 weeks. After 4 weeks it will be recommended to patients that they start to taper the splint (e.g., use only as a night guard) in preparation for discontinuing the splint altogether. The purpose of this is to try to prevent the patient from becoming so comfortable with the splint that he/she starts clenching or grinding on the splint itself. (Patients will not have to stop using the splint if they continue to find it useful).

   In addition to the splint, patients will also be given a 14-day course of non-steroidal anti-inflammatory medication (NSAIDs) like Naprosyn (550 mg twice a day) or Advil (600 mg three times per day). Extra strength Tylenol (350 mg three times per day) will be substituted for those patients who have difficulty with NSAIDs or who have gastric ulcer disease. A soft diet will also be prescribed with special attention paid to avoiding foods that require extreme jaw opening (e.g., large sandwiches) or foods that have caused pain in the past (e.g., steak). Patients will be asked to continue using the splint and the soft diet until the end of the 6-week treatment period, after which they will be informed that they may alter the treatment as they see fit (e.g., discontinuing the splint), but recommending care in their diet.

   The cognitive-behavioral (CBT) portion of the treatment will consist of 6 weekly sessions focusing on the development of skills for self-management of chronic orofacial/TMD pain. Because stress is such a large part of TMD pain, the skills discussed will include relaxation training and stress management, as well as finding new ways to think about pain. As noted above, these sessions may be conducted remotely, via telephone or teleconference.

2. The second type of treatment is Standard Treatment + Individualized Assessment and Treatment Program (STD+IATP). The 6-week STD+IATP treatment will include all aspects of the STD treatment described above (Splint, Non-steroidal analgesics, soft diet). In addition, patients will receive IATP. IATP involves 6 individual weekly sessions in which the therapist uses your detailed smartphone app recordings of your thoughts, feelings, behaviors, and situations to determine exactly what is contributing to your pain, and how best to help you manage that pain. Sessions focus on helping you to develop and use the skills that will work best for you. Again, these sessions may be conducted remotely, via telephone or teleconference.

Study Procedures

Intake Evaluation, Determination of Eligibility and Treatment Assignment. As part of the intake evaluation, you will be interviewed and asked to fill out questionnaires concerning many different aspects of your personal history, your pain, and any treatment you may have received. This will require about 1 hour of your time, and may be done online with guidance from a research assistant via teleconference. These questionnaires and instruments will be identified only by a code number previously assigned to you. Part of this interview will be used to determine if you are eligible for treatment in this study. In order to be assigned to a treatment, you need to be 18 or older, have significant jaw pain for at least the last 3 months, with the pain not related to arthritis or nerve problems (neuropathic pain), and not the result of surgery. Participants must also be English-speaking, and must not be using opioid drugs, or be pregnant (or planning on being pregnant), and must not have a serious psychiatric disorder.

As part of this initial evaluation you will receive a panoramic x-ray. This is an x-ray that scans the entire mouth in a single image, including the teeth, and the upper and lower jaws. This will be done to rule out any extensive damage to your temporomandibular joint that we would not be able to treat in this study. You will also be examined by one of our dentists in order to determine what kind of orofacial pain you have (e.g., muscle-related versus nerve related). This will involve pressing against your cheeks and jaw, and having you open and close your mouth.

If you are eligible for the study, you will be assigned to one of the 2 treatments described above after your intake evaluation. This assignment will be decided on a random basis (like the flip of a coin) using a computer program. After assignment to treatment you will have dental impressions taken in order to have a splint made for you. You will receive a payment of $40 for completing the intake measures.

Monitoring with the TMD pain smartphone app. Patients in both of the treatment groups will be asked to monitor pain during this study using a smartphone app. After you have been assigned to treatment, but before treatment begins, you will be introduced to the TMD pain monitoring app. After a demonstration, the monitoring system app will be loaded on your phone. The app will make your cell phone signal you four times a day between 8 a.m. and 10 p.m., every day for 14 days. This call schedule may be adjusted depending on your schedule. If you incur additional data use charges due to the use of the app we will reimburse you a total of $25 over the entire study.

If you do not have a smartphone we will provide one to you. If we do lend you a cellphone we will ask you to return it at the end of the study. Phones provided by us will be restricted so that they cannot be used to call friends or family, etc., cannot be used for texting, and cannot be used for internet browsing.

You will be asked to have your phone with you at all times while you are awake. The monitoring calls will be made at random times during the day. When you open the app you will be asked to enter your subject ID number. The system will then ask about any pain you might have had, and any medication or other things (cannabis, alcohol) you have taken to manage pain, along with your thoughts, feelings, behaviors, and current situation. You will be asked to respond to these questions within the cellphone app.

> *For example*, you may receive a signal from your phone at 9:13 AM on a Tuesday. When you open the TMD app the system will ask for your study ID number. Once you enter your ID, the system will show you a sliding scale from 0 (No Pain) to 5 (Worst Possible Pain) so that you may indicate your current level of Jaw Pain – Left Side. Another sliding scale will ask about Jaw Pain – Right side. Other questions presented in the same way will ask about mood states and your current thoughts about your pain problem. A number of questions will be asked in this manner. The total time using the app should be about 2 minutes.

You will be trained how to use the cell phone app to answer these questions. After the 14 days are up treatment will begin. Because answering these questions is so important, we will offer an incentive for doing the cellphone monitoring. You will be paid $5.00 for every day that at least 3 recordings are completed, and a bonus of $5.00 a week for each week in which all calls are completed. The possible total incentive will thus be $40.00 per week, or $80.00 total in the 2 weeks before treatment begins. These payments will be calculated on the day of your first treatment appointment, and will be paid out by check, made payable to you. The check may take 5 to 10 days to arrive. If possible, and if your prefer, we may be able to pay you via e-gift card (e.g., Amazon gift card), that would be sent to you in your e-mail.

Treatment. For all patients, treatment sessions will be conducted either in-person once per week, or remotely via teleconference once per week. The decision to pursue treatment remotely will be made with your therapist. The scheduling of treatment sessions will also be arranged between you and your therapist. Treatment is scheduled for 6 sessions. You will have 10 weeks to complete the 6 sessions.

Even if treatment is primarily conducted remotely, you may be asked to schedule a time to pick up written materials at the Health Center. These materials include guides, worksheets and other materials used in treatment.

Regardless of which treatment you receive, the therapist will ask you to try to make changes in your behavior and to work on new skills between treatment sessions ("homework") to help you manage your pain problem. Between-treatment assignments might include practicing relaxation, or keeping track of your teeth grinding and/or clenching. All treatments will be delivered by highly experienced therapists who have been specially trained to provide the treatments in this study.

At the first treatment session, 2 weeks after the intake visit and following the first round of cellphone monitoring, all participants will have their splints delivered and fitted by the dental assistant or oral surgeon. You will receive advice regarding use of the splint, advice on soft diet, and delivery of a 2-week supply of NSAIDs with written instructions. This first treatment session, including delivery of the splint, will take about 1 hour 30 minutes for all patients. Sessions 2 through 6 should each take about 1 hour.

Transportation to Study Visits

You will be responsible for your own transportation to treatment sessions. However, it may be possible to issue CT Transit bus passes in cases of emergencies, or if transportation is temporarily unavailable. If you have trouble with the costs of driving to UConn Health we may be able to provide gift cards for gasoline. During the Covid pandemic, study visits may primarily be conducted remotely.

Audiotaping. If you give your consent, all treatment sessions will be audiotaped for the purpose of evaluating the services you receive and monitoring the treatment provided by the therapist. If you do not want to consent to this taping please indicate by placing your initials on the line below.

➔ I do not consent to audiotaping_____(initials)

Audio recordings will be labeled only by coded ID number, and will be kept in password-protected files. Only the clinical supervisor, the research assistants, and the therapists will have access to audio recordings. Identifying information will not be disclosed on the recordings; that is, they will not be labeled by name, and no information that could be used to identify you will be recorded. If necessary, recordings will be edited to remove any information beyond your voice that could be used to identify you. Recordings of treatment sessions will be deleted when the study is complete. If you decide not to permit audiotaping that decision will not prevent you from participating in the study. You can change your mind about being recorded at any time.

During-Treatment Smartphone Monitoring. In order to detect changes in habits that might be occurring due to treatment, you will be asked to do the TMD monitoring again at Week 2 of treatment for 7 days, and at Week 4 of treatment for 7 days. The monitoring will be done the same way as the pretreatment monitoring. As in the pretreatment period, the possible total incentive will be up to $5 per day for near-complete recording, or $40 for each week of monitoring.

Post-treatment Interview and Monitoring. At the end of the treatment period you will be asked to meet again with the research assistant and complete post-treatment questionnaires about your pain, any treatments you might have received, and what you have learned in treatment. The session will take about 1 hour, and may be done remotely. You will receive $25 for completing the post-treatment assessment.

Once again you will be asked to do the TMD smartphone monitoring for a period of 7 days. As before, the possible total incentive will be $40 for the week of monitoring.

Follow-ups. Follow-up interviews will be conducted via online RedCap surveys and Webex teleconference at 3, 6, 9, and 12 months. You will receive $25 for completing each follow-up visit. In addition, at 3 months, and again at the end of the study at 12 months, you will be asked to respond to the TMD monitoring app for 7 days. These monitoring periods will allow us to see what changes may have occurred in your momentary pain and mood state after treatment. Again, you will be compensated up to $40 for the week of recording at each follow-up period.

In summary, your involvement would consist of the following phases:

2 weeks of pretreatment monitoring, 6 sessions of treatment, and about 9 months of post-treatment follow-ups. This adds up to 13-14 months of involvement with this study, with total possible compensation of $445 over the entire study.

It is very important that we be able to find you during this project, so that we may get information, but also so that we can check on your status and provide help if needed. To help us keep track of you we will ask you to provide names of a few people we call Locators (e.g., spouse, adult child, parent, other relative or friend), who will know your whereabouts over the next 13 months, to help the research staff locate you if you change your address without notice or become indisposed for some reason (e.g., hospitalization). These people may be contacted if we are unable to locate you. They will not be asked about your pain or medication use. If no one can find you, we are asking you to agree that public information sources, such as telephone directories, motor vehicle records, Social Security Office information, or public locator services, may be used to find you.

We are also asking you to agree to allow us to use social media, through private messages, to contact you if that becomes necessary. (Private messages through social media will alert you that a follow-up interview is due, and that we will compensate you for your time). If you agree, we will also try to contact you through e-mail, text messaging, mail and telephone. If we cannot arrange for you to follow up with us in person or on the telephone, as a last resort we will mail you the relevant questionnaires, along with a paid return envelope, to be completed at home. You will receive a check in the mail made payable to you for $10 for completed packages that are returned to us.

You will be asked to provide your Social Security number for use in locating you, if necessary. Because your information is so valuable, we may try to contact you multiple times, through a variety of means, if we lose track of you. Even if you decline or stop treatment we will still want to get information about you. If at any time you wish us to stop trying to reach you, you must explicitly inform us that you wish to withdraw from all aspects of the study, including follow-ups. All information that you provide to us will be handled in a confidential manner.

Reporting alcohol or non-prescribed drug use. Throughout this study you will be asked to tell the research staff about any times you use alcohol or other drugs to help manage your pain while in the study. The staff realizes that people in pain may have to resort to these substances to manage. In order to be helpful to you and to others, they need to know about your alcohol or drug use (including cannabis). Because of the serious risk of opioid dependence and overdose that exists in chronic pain populations, we also need to know about any prescribed or non-prescribed opioid medication you may be using. This includes OxyContin, fentanyl, and heroin. We will not report any such use to the police. We may, however, offer you counseling or additional resources if needed.

Timeline. The overall schedule will be as follows:

Timeline	Activity
Pretreatment Weeks -2 and -1	Daily recording of pain, mood, etc., by TMD app before starting treatment x14 days
Weeks 1-6	Weekly treatment in person or conducted remotely
Week 2	Daily recording of pain, mood, etc., by TMD app x 7 days
Week 4	Daily recording of pain, mood, etc., by TMD app x 7 days
Week 6-7 (Treatment End)	Post-treatment Interview via online surveys and teleconference Daily recording of pain, mood, etc., by TMD app x 7 days
Week 12 (Month 3)	Follow-up Interview, via online surveys and teleconference. Daily recording of pain, mood, etc., by TMD app x 7 days
Week 24 (Month 6)	Follow-up Interview, online surveys and teleconference
Week 36 (Month 9)	Follow-up Interview, online surveys and teleconference
Week 48 (Month 12)	Final Follow-up Interview, online surveys and teleconference Daily recording of pain, mood, etc., by TMD app x 7 days

Risks and Safeguards

Clinical Deterioration. As with any treatment for a medical issue, you could experience clinical deterioration (worsening of your pain problem or other life issue) during the course of the study, especially if the treatment to which you are assigned is not effective in your case. Such risks are not foreseeable. The research staff and therapists will monitor participants in both of the study treatments for signs of deterioration, and will refer you for more intensive treatment if such a problem arises. If you pursue treatment outside the study, you will be responsible for the costs of that treatment.

Panoramic X-Ray. In order to rule out jaw disorders that we cannot treat in this study we will perform a panoramic x-ray. A dental x-ray will expose you to some radiation. The estimated radiation exposure received by each participant for the panoramic view is 1.5 millirem (15 uSv). This dose equivalent would be less than that received by an individual flying from New York City to San Francisco.

Discomfort with Splint. All participants will be fitted with a splint, or mouth guard, placed on the upper teeth. Some people may find this uncomfortable at first. If discomfort occurs, you may contact the study dental assistant or research assistant, and we will arrange to see you promptly (within a couple of days) to make adjustments to the splint. If the discomfort continues, you may stop using the splint at any time.

Discomfort from use of medication. As part of treatment all participants will be prescribed a non-steroidal anti-inflammatory drug (NSAID), something like Advil (ibuprofen). Sometimes these medications can cause discomfort, like upset stomach. Prior to any prescription, one of the study dentists will ask you about your history with these kinds of medications. For those who are sensitive to NSAIDs, another medication such as extra-strength Tylenol will be prescribed. For those who do receive an NSAID and develop discomfort, that drug will be discontinued and another drug prescribed instead.

Confidentiality. Another potential risk is a possible breach of your confidentiality. Although we cannot guarantee that confidentiality will be maintained, the researchers will make every effort to maintain your confidentiality. Your research record will be labeled with a code number, which will be determined using a random numbers list. A master list that links your name with your code number will be maintained in a separate and secure location. Consent forms will be stored in a secured location (e.g., a binder in a locked file cabinet) apart from the research record. Your name will not appear in any publication. Only those associated with this study will have access to your research record, or to the master list linking your name with your code number. If your information is used in future research, all identifiers, such as name and date of birth, will be removed. After removal of names and other identifiers, the information you provide could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you, the subject.

You will be instructed in ways to prevent disclosure of sensitive information while participating in TMD app monitoring (e.g., how to keep from being overheard or observed while using the app; how to delay

responding to a signal), and while completing paperwork related to treatment assignments. Because someone other than you could pick up your cell phone, the system will not identify itself when it signals a recording. The user will only see: "This is an online survey. Please enter your ID number, and click the 'Submit' box." If the ID number is not entered within 15 seconds, the app will ask if the person needs more time. ("If you need more time, click Re-enter ID"). If there is no response the app will close and repeat the recording attempt 15 minutes later. The monitoring data themselves will be stored on a secure server maintained by our technical partner. Access to these data will be by password only. The data themselves are identified only by code number, and no identifying information will appear in the monitoring records.

A Certificate of Confidentiality has been obtained to further help protect your privacy and the confidentiality of your data. With a Certificate of Confidentiality in place, the investigators cannot be forced to disclose research-related information about you to anyone not connected to the study, except in very limited circumstances. A Certificate of Confidentiality does not stop you from voluntarily disclosing information. It also does not stop the investigators from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The information collected for this research study will be accessible to authorized persons. Authorized persons include study team members, representatives of UConn Health and, as may be applicable, representatives of the Sponsor and/or representatives of Federal agencies when required by law, such as the Department of Health and Human Services when the research is federally funded or supported. Representatives from these areas have access to the information so they may ensure that the study is being done correctly.

Participant Burden. Carrying and answering the smartphone for TMD monitoring can be annoying. This has sometimes been a complaint in others who have monitored pain and other sensations. Most people have not found the phone to be very annoying, however, and have said later that they have learned a lot from doing the monitoring. You will be compensated for successfully completing self-monitoring.

Discomfort with Personal Questions. Some people may feel uncomfortable about answering personal questions. Unfortunately, we must ask about a lot of personal issues in order to conduct this research. Participants are free to decline to answer any questions, and may withdraw from the study at any time.

Disappointment with Treatment Assignment. On occasion someone might be disappointed with their assigned treatment. Both of our treatment conditions contain treatment elements that are found in other treatment programs, and all have demonstrated effectiveness. Thus, none of our participants will be deprived of anything that they might have obtained in a program elsewhere. The one exception to this is the prescription of narcotic pain medication. We will not be supplying or prescribing narcotic pain medication in this study. If a subject is dissatisfied with the intervention to which he/she is assigned, referral will be made to a treatment setting outside of the study.

Exposure to potentially stressful circumstances. Some people may find the effort to manage pain itself to be stressful, due to lifestyle changes, etc. However, there will be no greater distress in this study than in any other effort to comprehensively manage a chronic pain problem. In addition the level of support provided by staff in this project is very high, and will help diminish the stress associated with treatment. Also, the homework and TMD monitoring activities might be seen as stressful. In order to minimize risk of upset to participants the patient and therapist will negotiate homework assignments, and problem-solve ways to make assignments as successful as possible.

Costs of participation. Treatment is provided at no charge to you. There are no additional costs associated with participation in this research above those associated with receiving outpatient treatment for orofacial pain in any other setting (e.g., travel expenses, etc.). You may have to take time from work in order to participate in study visits. You may incur some travel costs to get to study visits. We will schedule follow-up visits at your convenience to minimize costs. If travel to UConn Health is difficult we may provide bus passes, if that would make it easier.

Benefits
There is no guarantee that the treatment you receive will benefit you. However, you may experience benefits such as improving your sleep or functioning, or other improvements in your life. Even if there are not specific benefits for you personally, this study may provide information that can help others in the future.

Stopping Study Participation
You could be dismissed from the study, or referred for treatment outside the study, if you repeatedly fail to show up for appointments, if you cannot adhere to the TMD monitoring procedures, if you are taking opioid pain medication, or if you are repeatedly under the influence of substances at the treatment sessions or interviews. Your obligation to the study is to do your best to work to manage your pain problem, to be honest with the therapist about yourself and your problems, and to be available at the right times for treatment sessions and assessments.

Alternative Treatments
Participants may opt to not pursue treatment in this study. There are pain programs available in other facilities that may offer treatment. If a participant desires a referral we will work to provide that.

Voluntary Participation
Your participation in this research is completely **voluntary**. You are free to choose not to participate. If you do participate, you are free to withdraw at any time. If you choose not to participate, or if you withdraw from the study, it will not harm your relationship with the clinics or doctors at UConn Health. You may discontinue study participation at any time without penalty or loss of benefits to which you would otherwise be entitled. A list of alternative treatment providers is available upon request, and the staff can assist you in selecting among them.
Any significant information we discover that might influence your decision to continue participation will be communicated to you in a timely way.

If you do wish to discontinue your participation in this study you may contact your therapist, or your research assistant: Kara Dion (860-679-4767), Abi Young (860-679-3718), Diane Wilson (860-679-3020), or Jane Harrison (860-679-4765). You may also call the clinical Coordinator, Elise Kabela-Cormier (860-679-2657), or call or write to the Principal Investigator, Dr. Mark Litt (860-679-4680) at the Division of Behavioral Sciences, UConn Health, Farmington, CT 06030-3910.

Sharing of Information

We receive money from the National Institutes of Health (NIH) to do this study. NIH requires that we have a plan in place to share information we gain in this study. We anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study.

Your information will only be shared in an anonymous way. Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you provide permission now to share your anonymized (unidentified) information with the database noted below, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

The anonymized information from this study will be placed in a Data Coordination Center maintained by the National Institutes of Health. The information will be freely available in a public, unrestricted database that anyone can use for future research. The public database will include information on the pain, medical symptoms and questionnaire findings of thousands of people in studies like this one. The only health information included will be whether you had TMD/orofacial pain or not. This public information will not be labeled with your name or other information that could be used to easily identify you. Please indicate whether we may share your anonymized information by initialing your preference:

Yes, my anonymized information may be shared for future research _____(initials)

No, do not included my anonymized information in the data that is shared _____(initials)

Participant Injury/Adverse Events

Every effort to prevent injury as a result of your participation in this study will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. If at any time during treatment, or during the follow-up period, you experience a serious problem, you may contact the study staff (860-679-2657) to request referrals for additional treatment. UConn Health does not offer free care. However, treatment for a research-related injury can be obtained at UConn Health for the usual fee. UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-4849 or 860-679-8729.

Questions/Comments

Your therapist, or a therapist on call, will be available by calling the Project Coordinator, Dr. Elise Kabela-Cormier, at 860-679-2657, or the Principal Investigator, Dr. Mark Litt, at 860-679-4680. You will be encouraged to call if you have any questions or problems. Drs. Litt and Kabela-Cormier are available during business hours, Monday through Friday. For problems that occur after business hours patients should contact 911, their local emergency room, or Infoline for non-emergency services. You will be given a list of emergency and non-emergency services and their phone numbers to be used if needed.

You are encouraged to ask about anything you don't understand, and to consider this research and the consent form carefully before you agree to participate. You may take as much time as necessary to think it over.

You may also call a coordinator at the Institutional Review Board (860-679-4849 or 860-679-8729) if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies. Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Other Information

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 web site will include a summary of the results. You can search this web site at any time. If you wish, you may request that a summary of the results be sent to you once the study is completed. We will not be able to provide you with information specific to you personally.

You may also request that your records be released to your personal physician. If we release study records for clinical care purposes, then we will remove all identifying information from your records prior to releasing them.

This project provides compensation to participants. Our general practice is to issue checks payable to a participant by name. Because of this, you must either bring identification to pick the check up in person or have it mailed to you. You can also choose not to receive any compensation. If you do choose reimbursement by check no reference to this study will appear on the check ledger line. *We are required to advise you that if you receive over $600 from participating in research studies over the course of a calendar year, that money must be reported to the IRS as income, and a signed W-9 form may be required in that circumstance.* (The total compensation from this study will be less than $600).

Please indicate your preferences by initialing below (You may change this at any time):

I prefer not to receive compensation for this study _____
I will pick the check(s) up in person_____
I would prefer the check(s) be mailed to me____
If possible, I would prefer an e-gift card to be sent to my e-mail_____

We would also like your permission to contact you in the future regarding this or other research. At this time we have no plans to contact you further, but we are asking your permission in case it might be useful to reach you again. You are not required to agree to this additional contact, and we will not attempt to contact you more than 12 months after your last meeting with us in any case. If we do contact you in the future we will not refer to any previous study participation. Would you agree to be contacted in the future?

☐ **Yes, I agree to be contacted in the future**

☐ **No, I do not agree to be contacted in the future**

Consent to Participate

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study and been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

You will also be given a Participant Feedback Form that you may complete and submit to Institutional Review Board to provide information about your general experience as a study volunteer for purposes of quality improvement. You may use this form to offer suggestions, express concerns, complaints or compliments about your involvement in a research study, or to ask general questions or obtain information about participation in other clinical research studies.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of the signed document will be provided to the subject.

Role			**Date**
Participant	**Printed Name**	_____	
	Signature	_____	_____
PI or authorized research personnel	**Printed Name**	_____	
	Signature	_____	_____