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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw.

We aim to create an environment of mutually respectful interactions between research staff and participants. We pledge that research staff will not engage in disrespectful behavior or use racist, sexist, or other inappropriate language, and ask the same of you. If you have questions about your rights as a research subject, or have concerns regarding the conduct of research staff during your participation, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Acute Effects of Alcohol Use on Chronic Orofacial Pain

3. Who do you call if you have questions about this research study?

Jeff Boissoneault, PhD, Principal Investigator (352-273-6147)
Michael Robinson, PhD, Co-Investigator (352-273-6617)
John Neubert, DDS, PhD, Co-Investigator (352-273-5687)

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4. Who is paying for this research study?

The sponsor of this study is National Institute on Alcohol Abuse and Alcoholism (NIAAA).

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

You are being asked to be in this research study because you are a healthy current drinker between the ages of 21 and 45 who may or may not have chronic jaw pain, including temporomandibular joint and muscle disorder (TMD). You should not be in this study if you:

- Have a medical history or condition that would conflict with study participation, including chronic pain other than jaw pain
- Are unable to speak and read English
- Are currently participating in another research study that could interfere or influence the outcomes of this study
- Are unable to provide informed consent
- Have a history or presence of psychiatric, psychological, or neurological disorder(s)
- Have not had at least one drink containing alcohol per month over the past six months
- Have a serious medical illness (e.g., hepatitis, HIV/AIDS)
- Have a history of drug or alcohol dependence
- Currently use opioid medications on a regular or as-needed basis for any reason
- Regularly smoke cigarettes or use tobacco/nicotine products

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to test how alcohol affects sensory function in people with and without chronic facial pain. This study has 3 total sessions. Your screening visit will take approximately 1 to 2 hours, and the 2 laboratory sessions will require 4 to 8 hours each. These sessions will typically occur over a period of about 2-3 weeks.

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b) What is involved with your participation, and what are the procedures to be followed in the research?

Participating in this study involves 3 different visits to our laboratory, including this screening session. During screening, you will complete a number of questionnaires and pressure-based pain and sensory testing. During the following two laboratory sessions, you will consume a beverage that may or may not contain alcohol and undergo the same pressure-based testing. We provide transportation to and from laboratory sessions using a rideshare service (Uber or Lyft). See Item #7 below for additional details.

c) What are the likely risks or discomforts to you?

Briefly, potential risks involved with participating in this study include alcohol intoxication and discomfort from the pressure testing. Other potential risks and discomforts are described in detail in Item #10 below.

d) What are the likely benefits to you or to others from the research?

There is no direct benefit to you for participating in this study. However, society-at- large and the medical community may benefit by enhancing our understanding of how alcohol affects pain and sensory function in people with and without chronic facial pain.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Participating in this study is entirely optional. This is not a treatment study. If you are a faculty/staff member or student at the University of Florida, your decision whether to participate will have no impact on your employment or academic status.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read carefully before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Your normal clinical care will not be affected by participation in this study.

7. What will be done only because you are in this research study?

Initial screening procedures will include:

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a) After arriving at the Center for Pain Research and Behavioral Health (located on the ground floor of the UF Dental Tower in room DG-64, 67, and 68), the Informed Consent form will be reviewed with you to make certain that you understand everything that is involved in the study procedures. All study procedures will take place within a private testing room.

b) You will complete several questionnaires about your demographics (age, education, etc.), family history of drug and alcohol use (including nicotine), typical drinking behavior, affect and personality, attitudes about alcohol, beliefs about pain, and medical history.

c) If you have jaw pain, Dr. Neubert will complete a brief orofacial pain assessment to determine the type of jaw pain that you have.

d) You will complete sensory testing, which involves application of pressure to the face at the insertion of the masseter muscle. The masseter muscle assists with chewing foods. During this procedure, we will mark this location on your face with ink. Using a device called a “pressure algometer”, we will determine what level of pressure is painful to you and ask you to rate the level of pain, if any, you experience when specific levels of pressure are applied to this location. You can discontinue the procedures at any time so you do not experience pain you find intolerable.

The 2 laboratory sessions involve the following procedures:

a) Both laboratory sessions occur in our laboratory (DG-64/67/68). You will be asked to fast for at least 4 hours prior to your scheduled session and abstain from alcohol consumption 24 hours before each session. You should also avoid taking non-steroidal anti-inflammatory drugs (NSAIDs) in the 12 hours before your session. You should also not take any OTC medications (including allergy medications and analgesics) in the morning before your session. Normal morning medications are generally permitted but you should not take any medications that may have harmful interactions with alcohol. This includes drugs that may make you drowsy, like opioid-based medications or benzodiazepines. If you are not able to meet these requirements, please let us know as soon as possible so your laboratory session can be rescheduled.

b) We will provide transportation to and from the laboratory using a ride-share service (Uber or Lyft).

c) You will be screened via urine analysis for recent use of disqualifying drugs, including marijuana, cocaine, benzodiazepines, morphine, and methamphetamine.

d) You will also be initially screened for recent alcohol consumption using a standard breathalyzer, which must be negative. If results of this test or the urine drug screen are positive, you will be discontinued or your session will be rescheduled at the PI’s discretion.

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e) If you are of childbearing potential, you will be given a pregnancy test. If the test is positive, the results will be destroyed and you will be discontinued from the study. The study team will recommend that you contact your physician.

f) You will be provided with breakfast and a light lunch.

g) You will complete paper/pencil mood assessments of your mood.

h) You will be given your beverage, which will consist of alcohol (if any) mixed with sugar-free lemon-lime soda. Once finished, you will be asked to rinse your mouth thoroughly with water.

i) You will then be asked to complete assessment regarding your intoxication level. You will also periodically breathe into a breathalyzer.

j) After drinking the beverage, you will complete brief paper/pencil assessments and undergo pressure-based sensory testing like that conducted during the screening session.

k) After testing is completed and your breath alcohol concentration is at or below 0.02 g/dL, you will be transported home using Uber or Lyft.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

This study has 3 total sessions. Your screening visit will take approximately 1 to 2 hours, and the 2 laboratory sessions will require 4 to 8 hours each. These sessions will typically occur over a period of about 2-3 weeks.

9. How many people are expected to take part in this research study?

Up to 110 people may be screened for this study. Our goal is for at least 50 people to complete all study procedures.

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WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

This study might involve the following risks and discomforts to you:

- You may feel intoxicated after consuming the alcohol dose used in this study. Alcohol consumption may result in nausea and/or vomiting, as well as drowsiness, gastrointestinal upset, impaired memory and concentration, and decreased inhibitions. This may result in impairment to your normal function. However, the alcohol effects will have worn off by the end of laboratory sessions and assurance will be made that you are not intoxicated before you are transported home.
- You may feel uncomfortable answering questions about private topics during screening and laboratory sessions. However, you may choose not to answer any questions that make you feel uncomfortable.
- Certain medications may have harmful interactions with alcohol. For this reason, you will not be allowed to participate in the study if you use prescription medications that cause drowsiness (for example, benzodiazepines or opioids for pain).
- There are minimal risks associated with our pressure sensory testing. This includes pain that is not expected to last for longer than 90 seconds. The testing procedure may be uncomfortable or unpleasant; however, if the pain is greater than you wish to tolerate, you may discontinue the procedures at any time without penalty. It is possible, but very unlikely, that bruising could result from this procedure.
- Other possible risks to you may include dizziness or lightheadedness from breathalyzer testing.
- There is a risk of spreading or contracting COVID-19 during participation in this study. We are taking the following steps to limit spread of COVID-19:
    - During screening visits, which do not involve the use of a breathalyzer, research staff will wear a disposable Level 1 surgical mask during all interactions with you or other staff members. During laboratory visits, which do involve the use of a breathalyzer and production of aerosols, research staff will wear a KN95 mask. If you arrive for a study session and do not have a mask, please wait outside the Shands Dental Tower West Entrance, inform our staff of your arrival (352-273-5220), and wait for a research assistant to come outside and provide you with one. You are required to wear the mask for the duration of all sessions, except

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when otherwise instructed (e.g. when drinking a beverage or providing a breath sample).

- If you are not willing to wear a mask, we ask that you do not participate in this study.

- At the beginning of each study session, all screening material documents will be presented to you. You will be instructed when to flip to the next page, to reduce the number of times forms are passed between people. Writing instruments will be designated for participants and disinfected between study sessions.

- All study equipment will be sanitized before and after each use. Study equipment includes, but is not limited to: tabletops, door knobs, clipboards, pressure algometers for QST procedures, beverage tray, and breathalyzers.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

To help us protect your privacy, we have been granted a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

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It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit to you for participating in this study.

11b. How could others possibly benefit from this study?

Improving understanding of how alcohol use affects pain and sensory function in people with chronic orofacial pain conditions like jaw pain and TMD may allow us to make better recommendations for reducing risk associated with drinking.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Participating in this study is entirely optional. This is not a treatment study.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

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If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you choose to withdraw from the study, no new information will be collected. The information already collected could still be used to complete the study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The study is cancelled and/or discontinued, or other administrative reasons.
- You have an adverse reaction to the alcohol dose or pain sensitivity testing.
- You have recently used medications or drugs that are not allowed, or you are pregnant.
- You have not followed pre-test instructions.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no cost to you for participating in this research study.

15. Will you be paid for taking part in this study?

Yes. You will receive a $15 gift card for completing the screening session, and your gift card will be loaded with $50 for each laboratory session. The total amount you will be paid for completing all study procedures is $115. You will receive partial payment if you do not complete all study procedures.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information, which will include your name, address, and date of birth, is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity. The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and

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Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information will be gathered only through your self-report, participation in study procedures, or from your study visits or telephone calls. More specifically, the following information may be collected, used, and shared with others:

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a) Your name, research record number, contact information, and dates associated with tests related to your participation
b) Social security number (for payment purposes)
c) Date/time of negative pregnancy tests (results of positive tests are destroyed)
d) Demographic and health status information
e) Responses to questionnaires
f) Results of laboratory tests

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others to determine how alcohol intake affects pain and sensory function in people with and without jaw pain conditions, including TMD.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

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20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- Research staff at the University of Florida associated with this project.
- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date