UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: mRNA changes induced by exercise in patients with chronic orofacial pain

Study No.: HP-00085798

Principal Investigator:
Luana Colloca, MD, PhD
410-706-8244 (office)

CONCISE SUMMARY:

The study we are asking you to participate in is being conducted by Luana Colloca, MD, PhD at the University of Maryland School of Nursing (UMSON). This study is for research purposes only and your participation is completely voluntary. You may choose not to participate. Even if you initially consent to participate, you can withdraw at any time.

The purpose of this study is to explore the effects of exercise on OMICS, which are biological factors that may predetermine the ways we cope with pain. If you choose to participate in this study, the research team will send you an electronic link to complete some surveys and scales. After completing the surveys, you will be scheduled to come to the lab for a blood draw. At this time, you will be provided with study equipment and information, with instructions for use during a four-week study period, and you will be randomly assigned to one of two groups that will be asked to do different activities as part of the study. At the end of the study timeframe, you will come to a second lab visit similar to the first day's visit. Each visit will take approximately one hour. You will be in the study for a total of four weeks.

The greatest risks of this study include the possibility of physical discomfort with the pain tests and blood draws, and the loss of confidentiality.

You will receive payment for being in this study: a maximum of $95 for each visit, for a potential grand total of $190. The payment will be in the form of an electronic gift card.

PURPOSE OF STUDY

We are asking you to participate in a study that explores how exercise in people with Temporomandibular Disorder (TMD) pain affects OMICS. We are recruiting 60 participants with TMD but otherwise in good health for this study. You are being asked to be in this study because you were in a similar one before.

PROCEDURES

If you agree to join the study, you will be put in one of two groups that differ in the type of activity they will be asked to do for the study. One group will do TMD exercises and the other group will not do any exercises. People in the group doing the exercises will receive daily text messages. People in both groups will wear a small wrist device to measure how active they are during both waking and sleeping hours.

The device will be worn for the entire duration of the study . The group you are put in will be chosen by chance. Neither you nor the study leader will choose your group. You will have an equal chance of being in either group. A flip of a coin will determine in which group you will be placed.

The entire study will last four weeks. At the beginning of the study (week 1) and at the end of the study (week 4), you will attend clinic visits at the School of Nursing Clinical Testing Suites. There are a total of two visits that will take 15 minutes each. Project activities and confidentiality are described below:

1. *Blood Samples (~8-14 minutes)* – At each visit we will collect a little over 3 teaspoon of blood for a total of 6 teaspoon for the entire study. This bloodwork is to measure inflammatory, hormonal, and genetic factors that may be related to your pain. The blood samples will be drawn by trained members of the Research Team. You have the right to decline to give a blood sample, but in this case you will be unable to participate in the study.

   _____ I consent to giving a blood sample (may participate in the study)

   _____I do not consent to giving a blood sample (may not participate in the study)

   These samples will not be used to find out if you have any diseases or health problems. They will be coded so that your identity is protected. The research team headed by Dr. Colloca will have access to the coded list. Your samples will be stored in locked refrigerators and freezers. Your samples will not be used to grow new cells. Information gained from these samples will not be provided to you nor to any of your medical providers. There is no limit on the time we may store your samples. We may continue to use it for research purposes until you provide a request, in writing, to withdraw from this study, or we stop the research study. If you decide to withdraw, no further information from these samples will be collected and your samples will be destroyed, though we may still retain any information that has already been collected up to this point.

   In order to analyze the information obtained from your sample, your information may be shared with researchers from the University of Maryland, other universities, the government, and drug- or health-related companies. The information from your samples may be shared with others outside the United States. The Principal Investigator will follow all existing federal and state privacy rules to keep your information private and confidential. Your name and other personally identifiable information will never be shared, except as required by law, and the research Investigator and Team will always take every step needed to ensure that your confidentiality and privacy are protected.

3. *Forms/Questionnaires (~ 45 minutes- 60 minutes)* – We will have you complete a series of questionnaires on-line at home that measure personality traits, depression, anxiety, pain symptoms, and medical history. There are several questionnaires that will take roughly 3 minutes each. Time spent on questionnaires over the whole study will be about 1 hour.

4. *Text Messaging Set-up (~5 minutes)* – If you have been placed in the exercise group, using the cell phone number you have provided we will conduct a test of the messaging system to ensure you can successfully receive the texts. Set-up will occur at the first on-line visit , but you will be free to contact us anytime during the study you wish to stop receiving text messages or if the

daily messages are not reaching you. Otherwise, text messages will stop once your time in the study is complete.

5. *Programming and Placement of Motionwatch 8 (~5 minutes)* – The device is lightweight and will be placed on your wrist. It is programmed to record your movements during both waking and sleeping hours, like a fitness or activity tracker. Placement will occur at the first visit. You will wear the motionwatch for the entire duration of the study, from the first week to the last week of the study. During this time you will be reminded, by either text or email, when you must put it on and when you can take it off during these time periods. Feel free to contact us anytime during the study you wish to stop wearing the device altogether. You may return your device at the time you stop wearing it, using a self-addressed-stamped-envelope, which will be provided to you, or in person during your last visit.

6. After completing this study, you may be eligible to participate in related, future studies. If you are eligible and you consent to be contacted in the future, you will be contacted by phone to set up an appointment to participate. At the time of this phone contact, you will also be given additional information about the study.

   _____I consent for my contact information to be used in the future if I am deemed eligible to participate in future related studies

   _____I do not consent for my contact information to be used in the future if I am deemed eligible to participate in future related studies

7. We may need to re-contact you for an additional information needed for this project, for example, another blood draw or additional questionnaires. We will mail or email you data collection tools.

   _____I consent to be re-contacted for additional collection of information

   _____I do not consent to be re-contacted for additional collection of information

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you are responsible for using your own cell or smartphone to receive text messages. You are responsible for wearing the MotionWatch 8 for the first and last weeks of the study. You are also responsible for attending the two visits—one at the beginning of the project and one at the end.

POTENTIAL RISKS/DISCOMFORTS:

The risks involved in this study are about the same as the risks involved in your normal daily life.

1. *Risks Associated with Blood Draw:* You may have some discomfort and bruising where the needle entered through your skin. There is also a very small risk of fainting. Infection in the area of needle entry is rare.

2. *Risks Associated with Filling Forms and Questionnaires:* You may experience some emotional discomfort, such as sadness or happiness, while answering questions on the forms or

questionnaires. If you feel uncomfortable in any way, study staff will be available to help you. Know that you are not required to answer any questions that make you feel uncomfortable.

3. *Risks Associated with Text Messaging:* There is the slight chance that other people may accidentally hear or see your text messages. To reduce this risk to your privacy we will only send texts that do not identify you, the school, the name of the study, or anyone related to the study.

4. *Risks Associated with the Motionwatch 8:* There is also the slight chance that you will experience some mild irritation or discomfort where the Motionwatch 8 is placed. If this occurs, you may take off the device.

5. *Risks Associated with Information Collected During the Study:* There is always a risk of your personal information being accidentally released when participating in any research study. We will reduce this risk by keeping your personal information separate from the other information we collect. Steps will include using only an assigned code number for your personal information including your contact information and name, on any documentation from this study. Electronic data will be password-protected and all paper copies of data will be stored in a locked cabinet. You will not be given the results of your questionnaires as this information is only being used for experimental and not clinical purposes. You have the right to access and disclose your records.

6. *Risks Associated with the Exercises:* There may be risks of some mild discomfort or muscle fatigue that feels like a light workout activity. These issues usually resolve in a day or two as you continue to do the exercises. We will show you how to do the exercises properly so that you don't experience any physical issues. If for some reason you have pain or discomfort that gets worse or does not go away, you may stop your participation in the study. You will still be compensated for the time you participated.

7. *Unknown Risks:* There may be risks or discomfort associated with participating in this study that are not yet known. You will be updated in a timely manner by study staff if any additional information is found that may affect your health and welfare. Based on any new information you may decide not to remain in the study.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation on this study. Exercises may help relieve your TMD pain. Findings from this study could add to research on how relief of TMD pain affects OMICS.

ALTERNATIVES TO PARTICIPATION

- This is not a treatment study. Your alternative is not to take part in it. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.
- If you do choose to be in the study but change your mind later, you may leave the study at any time. If you later choose to leave the study your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

- Research-related injuries are unforeseen and unlikely. However, if medical issues arise as a result of this study, we will provide you with assistance in finding medical care but costs incurred will be yours and/or your insurance company's responsibility.
- You will still need to pay for your cell phone and its monthly bill, as well as any charges for the text messages.
- This study will not have any extra costs beyond those described above.

PAYMENT TO PARTICIPANTS

- You will be compensated in the form of an electronic gift card (such as Amazon or Walmart) that will be given electronically , and you will receive a parking voucher as a token of appreciation for participating in this study.
- You will receive $65 for participation and $15 for the blood draw in the first visit (week 1). If an additional blood draw is needed for the first visit, you will receive another $15.
- You will receive another $65 for participation and $15 for the blood draw in the last visit (week 4). For the full study you will receive up to $190. Again, if an additional blood draw is needed for the second visit you will receive additional $15.
- In order to compensate you, we will ask for your social security number or visa number if you do not have a social security number.
- At each visit, you will be offered a parking voucher to cover 4 hours of parking.
- If you decide to withdraw from the study at any time during or at the end of the process, you will still be paid. You can expect the electronic gift card to arrive in through email approximately 4-6 weeks.
- If you do not have a social security number because of your current visa status, your compensation will be provided in another form.
- This study will not have any additional payments beyond those described above.

CONFIDENTIALITY AND ACCESS TO RECORDS

Only Dr. Luana Colloca, the principal investigator, and her trained and designated research personnel will have access to confidential information. All confidential information that includes personally identifiable information will be coded with a code number. The principal investigator and study point of contact will be the only individuals with access to the key of the assigned code numbers. All confidential information will be locked in a cabinet in a secured location at the University of Maryland School of Nursing. Your personally identifiable information will not be used for this study's analyses but it will be kept on file if federal agencies, such as the Intuitional Review Board (IRB), are mandated to review any information.

All study records will be considered confidential, and all participants' names and personally identifiable information will not be used in reports or publications. Efforts will be made to limit access to your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Those designated from the University of Maryland will be allowed examine certain research records of this study; however, anyone inspecting this information will do their best to keep this personal information confidential. Your personal information will not be released unless mandated by law.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Luana Colloca at 410-706-8244 (office), or point of contact, Rachel Massalee (443-854-4103), and Ana C. Duarte at 410-706-3047 (office) or 443-768-3052 (cell).
- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research. If you wish to withdraw from this study at any time, a written withdrawal request is required and should be sent to Dr. Luana Colloca at colloca@umaryland.edu. You will be informed of any findings in this study that may affect your willingness to continue participating.
- If you withdraw from this study, already collected data may not be removed from the study database.

CAN I BE REMOVED FROM THE RESEARCH?

The principal investigator, Dr. Luana Colloca, can remove you from the research study without your approval. Possible reasons for removal include incomplete data, abnormal or painful responses to the exercises, and non-compliance with completing tasks. The entire study can be stopped at any time by the university, investigator, Institutional Review Board (IRB), or the facility where the study is conducted. The principal investigator will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

☐ If you agree to participate in this study, please sign your name below.

_____ _____
Participant's Signature

Date:_____ Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

☐ If we can contact you for any future research studies, please sign your name below.

_____ _____
Participant's Signature

Date:_____ Date:_____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FORRESEARCH

Name of Study Volunteer: _____

Date of Birth:_____ **Medical Record Number**: _____

NAME OF THIS RESEARCH STUDY: Exercise For Chronic Orofacial Pain

UMB IRB APPROVAL NUMBER: *HP-00085798*

RESEARCHER'S NAME: *DR. LUANA COLLOCA*

RESEARCHER'S CONTACT INFORMATION: ***PAIN AND TRANSLATIONAL SYMPTOM SCIENCE DEPARTMENT***
University of Maryland School of Nursing (UMSON)
655 W. Lombard Street, 729A
410-706-8244

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Personal and family medical history, including information about past or existing, chronic or acute medical conditions and/or diseases.

Federal laws require this researcher to protect the privacy of this health information. She will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Colloca and her research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS).

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. She will stop collecting health information about you. This researcher might not allow you to continue in this study. She can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature:_____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.