RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Phase II - Open-Label Placebo consent form

Protocol Title: Chronic orofacial pain: Genetics, cognitive-emotional factors, and endogenous modulatory systems

Study No.: HP-00068315

Principal Investigator:

Luana Colloca, MD, PhD
410-706-8244 (office)
301-364-8089 (cell)

Sponsor: National Institute of Dental and Craniofacial Research (NIDCR)

CONCISE SUMMARY:

The study that we are asking you to participate in is being conducted by Luana Colloca, MD, PhD at the University of Maryland School of Nursing (UMSON). Participation in this study is entirely voluntary and even if you initially consent to participate, you can withdraw at any time. This form will explain the details of this study and will help you decide if you want to participate. After reading this form thoroughly and completely, please ask any questions that arise. You will be tested on your understanding of this form.

The purpose of this study is to offer open-label placebo pills called Zeebo® to investigate the potential to reduce pain and other outcomes. This is meant to extend the beneficial action of placebo effects that you have been exposed in participating in previous studies. Given your placebo responses, we will like for you to take placebo pills for the next 45 days once per day. In addition, we will monitor your pain experiences remotely via Qualtrics weekly for the initial 9 weeks, and monthly at month 3, 4 and 6.

Currently there are no known risks associated with Zeebo® placebo pills. However, we cannot rule out any risks or discomforts involved with Zeebo® and you can contact us prompt for any queries you may have.

This study is completely voluntary. We offer the Zeebo® placebo pills and you will receive a 25 dollars electronic gift card or check at the end of 6-month. Your alternative to participate is to not take part in this study.

PURPOSE OF STUDY

The purpose of this study is to explore how open-label placebo pills can potentially improve your behavioral and clinical outcome on pain experiences. This is meant to extend the beneficial action of placebo effects that you have been exposed in participating in previous studies.

PROCEDURES

The study will be completed remotely at your home. Following Phase II, you will take the *Zeebo*® pills 1x per day for 45 days. You have the right to decline to taking the *Zeebo*® pills.

_____ I consent to take the *Zeebo*® pills

_____ I do not consent to take the *Zeebo*® pills

You will be asked to record your pain experiences via Qualtrics: Weekly for the first nine weeks, and monthly at months 3,4, and 6. The procedure described below will occur only once and all participants from this study will undergo the procedure outlined below.

POTENTIAL RISKS/DISCOMFORTS:

1. *Loss of privacy and confidentiality:* There is always a risk for a loss of confidentiality when participating in a research study. However, every step to ensure the confidentiality and anonymity of your results and identity will be taken. Steps will include using only an assigned code number for your personally identifiable information, including your contact information and name, on any documentation from this study. Moreover, electronic data will be password- protected and all paper copies of data will be stored in a locked cabinet.

2. *Zeebo® pills risks:* The pills are composed of magnesium stearate and microcrystalline cellulose PH-102 (inert chemicals). There are no known risks associated with these pills.

3. *Unknown risks:* There may be unknown risks or discomforts involved with participating in this study that are not yet known. Study staff will update you in a timely manner if any information that may affect your health, welfare, and decision to remain in the study surfaces.

4. *Risks Associated with Psychological Questionnaires:* You may experience some discomfort while answering questions on the psychological questionnaires. However, you are not required to answer any questions that make you feel uncomfortable.

POTENTIAL BENEFITS

You will not benefit directly by participating in this study. However, findings from this study could add to research on how genetics can explain how individuals experience pain.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part,

your healthcare at the University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
Research-related injuries are seen as 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.

PAYMENT TO PARTICIPANTS
Participants will receive a total of $25, which will be processed at the end of the 6 months. Compensation will be in the form of an electronic gift card (e.g., Walmart, Amazon, Target, Safeway, and Visa card) or a check. We do ask that you allow 5-6 weeks for compensation processing. Participants will also receive a parking voucher as a token of appreciation for participating in this study. In order to compensate you, we will ask you for your social security number or visa number if you do not have a social security number. If you decide to withdraw your data at any time during or at the end of the procedure, you will still be paid. You can expect to receive your check in the mail within approximately. In order to compensate you, we will ask you for your social security number or visa number if you do not have a social security number.

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 will be the only individual 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 at 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.

RIGHT TO WITHDRAW
Your participation in this study is voluntary. You do not have to take part in this research study. You are free to withdraw your consent at any time. 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, you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the principal investigator, Dr. Luana Colloca at 410- 706-8244 (office) or 301-364-8089 (cell). There are no adverse consequences (physical, social, economic, legal, or psychological) for deciding to withdraw from this research study. If you wish to withdraw from this study at any time, a written withdrawal request is require 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 are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

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 pain sensitivity responses, 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.

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 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:_____

_____
Investigator or Designee Obtaining Consent
Signature

Date:_____

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

_____
Participant's Signature

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

Name of Study Volunteer: _____

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

NAME OF THIS RESEARCH STUDY: Chronic orofacial pain: Genetics, cognitive-emotional factors, and endogenous modulatory systems

UMB IRB APPROVAL NUMBER: *HP-00068315*

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.
- Medical chart information regarding TMD diagnosis and treatment

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.

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

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.