**University of Southern California**
Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, 1985 Zonal Ave, Los Angeles, CA 90089

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# INFORMED CONSENT FOR RESEARCH

**Study Title:** Trojan Cortisol Assessment and Laboratory Measurement (Trojan CALM)

**Principal Investigator:** Amanda M. Burkhardt

**Department:** Clinical Pharmacy

## INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

## DETAILED INFORMATION

### PURPOSE

The purpose of this study is to better understand stress in the university population and how stress changes in response to university events throughout the year (I.e., football games, exam weeks, move-in/move-out, returning from holiday breaks, etc.). We hope to learn about the relationships between stress/cortisol and a USC lifestyle. You are invited as a possible participant because you are an 18+ year old student or faculty member at the University of Southern California who is curious about the effects that physical and mental stress have on cortisol levels within you and your student/faculty peers at USC. About 1000 participants will take part in the study.

### PROCEDURES

If you decide to take part, this is what will happen:

- (1) A link will be provided to you that will generate an anonymous identification code which will be used to code saliva samples and questionnaires throughout the time of your participation in the study.
- (2) A weekly saliva sample will be collected from you that will be used to quantify your levels of cortisol. Saliva samples will be collected for up to 18 months, a maximum of 78 samples.
- (3) A weekly questionnaire/survey will be made available to allow a self-evaluation of your stress levels for that week. Surveys will be collected for up to 18 months, a maximum of 78 surveys.

- (4) If an email address is provided to the study team, a weekly email reminder will be sent out to complete the additional weeks of survey and saliva collection.

The tests done in this research study are for research purposes only and have no clear meaning for health care. However, these results will be accessible to you and other participants via the anonymous identifier code provided to you, throughout the study for your reference. Results will be posted a study webpage, you will be able to identify your individual cortisol reports using the anonymous identification code provided to you during enrollment. The data will be publicly available, but cannot be identified unless you publicize your own unique ID number.

## RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include.

**Surveys/Questionnaires/Interviews:** Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to.

**Breach of Confidentiality:** There is a small risk that people who are not connected with this study will learn your identity or your personal information.

**If enrolling USC Student Participants:** There is a risk that people who are not connected with this study will learn your identity or your personal information. Although highly unlikely, if your information becomes public, it might result in the university taking action such as referring you to Campus Support and Intervention (CSI) or Trojans Care 4 Trojans (TC4T).

- If you are pregnant, you cannot take part in this study.
- If you are breastfeeding and do not want to stop, you may not take part in this study.
- If you are under 18 years old, you cannot take part in this study.
- If you are a non-English speaking individual, you cannot take part in this study.

## BENEFITS

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn:

- If students and employees experience physiological stress at different times throughout the year?
- If there is a correlation between self-reported stress and physiological stress levels?
- What university events elicit population-wide spikes in physiological stress?
- If specific student populations (I.e., athletes, members of a specific major, students who commute vs live on campus, undergraduate vs graduate students, etc.) have different levels of self-reported and/or physiological stress?
- If different employee populations (I.e., faculty vs staff, full time vs part time) have different levels of self-reported and/or physiological stress?

## PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) and Human Subject's Protections Program (HSPP) may review your records.

Your responses, which are also called "data', and/or your specimens, such as blood or tissue, which are also called "samples" will be collected anonymously and will not be labeled with any personal identifying information or with a code the research team can link to personal identifying information. The physical specimens will be stored in restricted areas with access limited to study personnel. At the conclusion of the study, all specimens will be retained by the investigator for record keeping and potential future research; specimens will not be sent outside the institution to a third party. Electronic survey data will be stored with appropriate electronic safeguards with access limited to study personnel. Copying and use of study-related material will be restricted, and security software will be used on all study-related devices.

Your data and/or specimens collected as part of this research will be used or distributed for future research studies without your additional informed consent. Any information

that identifies you (such as your name) will be removed from the data or specimens before being shared with others or used in future research studies.

## ALTERNATIVES

An alternative would be to not participate in this study.

## PAYMENTS / COMPENSATION

You will not be compensated for your participation in this research.

## COST

There are no costs related to participation.

## VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

## WITHDRAWAL FROM STUDY INSTRUCTIONS

A courtesy email regarding your intention to withdraw from the study is appreciated, but not required.

## PARTICIPANT TERMINATION

You will be considered to have withdrawn if up to 20 consecutive weeks of consecutive inactivity have gone by.

## CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study primary investigator (PI). The PI, Amanda M. Burkhardt, can be reached at aburkhar@usc.edu or (323) 442-1463.

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.