

**UNIVERSITY OF CALIFORNIA IRVINE
INTRODUCTION TO THE HUMAN RESEARCH STUDY**

Health Status, Age, and Emotion Regulation among People with a Spinal Cord Injury

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NAME OF SUBJECT: _____

PURPOSE OF STUDY:

You have been asked to participate in a research project designed to understand physical and affective well-being among people with a spinal cord injury.

SUBJECTS:

You will be eligible to participate if you are over 18 years-old, have lived with a spinal cord injury for at least 5 years ago, and have not been diagnosed with a psychological disorder. This study will include approximately 250 participants with spinal cord injuries.

PROCEDURES:

If you agree to participate, the following will occur: You will participate in a one-hour initial interview over the phone. If you choose, this interview can be broken up into two ½ hour interviews. Following this interview, you will be called on the phone nightly for fifteen days and be asked questions about the events of the day, and your physical and affective well-being. Each nightly interview will last approximately 15 to 20 minutes. Parts of the nightly interviews may be audiotaped. These audiotapes will be secure and kept separate from your name and address. In addition, these audiotapes will be destroyed after they are transcribed.

On four of the interview days, you will be asked to provide saliva samples, in containers we will mail to you, at four pre-determined times (upon awakening, 45 minutes later, midday before lunch--sometime between 11:00 and 1:30 pm, and just before bed but prior to brushing your teeth). After completing the four days of saliva sampling, you will mail the samples back to the investigators in postage-paid envelopes.

Study Information Sheet
UCI IRB Approved: 3-9-07
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RISKS:

There are no foreseeable risks to answering any of the questions or providing saliva samples.

BENEFITS:

You understand that you will not benefit directly. You do understand, however, that you may gain insight into your daily experiences by thinking about the events of the day and answering questions about them each night. In addition, you will be helping researchers understand processes of daily life among people with a spinal cord injury.

COST/COMPENSATION:

You will be compensated \$50.00 for the initial 1-hour interview, and \$100.00 upon completion of the nightly interviews and saliva samples.

CONFIDENTIALITY:

You understand that your research records will be stored in a locked cabinet. The audiotapes will be kept separately from your name and address, and any other identifying information. The members of the research team included on this consent form will transcribe these audiotapes and destroy the tapes upon completion of these transcriptions. The research team, authorized UCI personnel, the study sponsor, and regulatory entities may have access to your study records to protect your safety and welfare. You understand that any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law.

In addition, any specimen(s) (e.g., saliva, tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California, Irvine (UCI). Once you provide the specimens, you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.

IF I HAVE QUESTIONS:

If you have any comments or questions regarding the conduct of this research or your rights as a research subject, you will contact the Office of Research Administration by phone, (949) 824-6068 or (949) 824-2125, or at 300 University Tower, Irvine, CA 92697-7600.

VOLUNTARY PARTICIPATION:

You understand that participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or quality of care at UCI Medical Center.

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