SAMPLE INTERVENTION/MEDICAL INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

[*Insert title of the study here.*] [*If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.*]

You are being asked to participate in a research study conducted by [*insert names and degrees of all investigators*], from the [*insert department affiliation*] at the University of La Verne. [*If student, indicate that results will be contributed to senior project, thesis or dissertation.*] You may participate in this research study if [*explain succinctly and simply why the prospective participant is eligible to participate*].

PURPOSE OF THE STUDY

[*State what the study is designed to assess or establish.*]

PROCEDURES

If you decide to participate in this study, we will ask you to do the following things:

[*Describe the procedures chronologically using simple language, short sentences and short paragraphs. This should be in language understandable by the target sample of participants. The use of subheadings helps to organize this section and increases readability. Terms should be defined and explained. Identify any procedures that are experimental.*]

[*Describe the procedure for the participants' assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.*]

POTENTIAL RISKS AND DISCOMFORTS

[*Describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed.*]

[*If there are significant physical or psychological risks to participation that might cause the researcher to terminate the study, please describe them and the possibility that the researcher may terminate the study without prior notice to participants.*]

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

[*Describe benefits to participants expected from the research. If the participant will not benefit from participation, clearly state this fact.*]

[*State the potential benefits, if any, to science or society expected from the research.*]

PAYMENT FOR PARTICIPATION

[*State whether the participant will receive payment. If not, state so. If participant will receive payment, describe remuneration amount, when payment is scheduled, and prorating formula should the participant decide to withdraw or is withdrawn by the investigator.*]

EXTENDED CARE OPTIONS FOR MORE THAN MINIMAL RISK RESEARCH

Note: The following is a required element of informed consent for research involving more than minimal risk. If this does not apply to your research, please omit this entry and delete the heading: *Explain whether any compensation/treatments are available if injury occurs and, if so, describe the extent and nature of the compensation or treatment. For research that may have lasting psychological effects, provide contact information for publicly available treatment options (e.g. hot or "warm" lines, student health services).*

CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of [*describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.*].

[*If information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.*]

[*If activities are to be audio- or videotaped, describe the participant's right to review/edit the tapes, who will have access, if they will be used for educational purpose, and when they will be erased.*]

PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so. [*If appropriate, describe the anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.*]

IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact [i*dentify research personnel: Principal Investigator, Faculty Sponsor (if student is the P.I.), Co-Investigator(s). Include day phone numbers and addresses for all listed individuals. For greater than minimal risk studies, include night/emergency phone numbers.*] .

RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, contact Sarah L. Dunn, Ph.D., IRB Director, at 909-448-4756, (irb@laverne.edu). University of La Verne, Institutional Review Board, 1950 Third Street, Kinesiology Department B108, La Verne, CA 91750.

SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I [(am over the age of 18 years) *include if population being recruited is over the age of 18 years*] and have been given a copy of this form.

_____
Printed Name of Participant

_____
Printed Name of Legal Representative (if applicable)

_____ _____
Signature of Participant or Legal Representative Date

SIGNATURE OF INVESTIGATOR (If required by the IRB)

In my judgment the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____
Signature of Investigator Date

Experimental Research Subjects Bill of Rights

California law, under Health & Safety Code 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.