

# **University of La Verne Institutional Review Board (IRB)**

For The

Protection of Human Participants in Research

## **General Requirements for Informed Consent**

Except as provided elsewhere in this or other subparts, no researcher/investigator may involve a

human being as a participant in research covered by these regulations unless the researcher/investigator has obtained the legally effective informed consent of the participant or

the participant's legally authorized representative. A researcher/ investigator shall seek such

consent only under circumstances that provide the prospective participant or the representative

sufficient opportunity to consider whether or not to participate, and circumstances that minimize

the possibility of coercion or undue influence. The information that is given to the participant or

the representative shall be in language understandable to the participant or the representative.

No informed consent, whether oral or written, may include any exculpatory language through

which the participant or the representative is made to waive or appear to waive any of the

participant's legal rights, or releases or appears to release the researcher/investigator, the sponsor, the institution or its agents from liability for negligence.

1. Basic elements of informed consent. Except as provided in paragraph (3) or (4) of this section, in seeking informed consent the following information shall be provided to each subject:

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. A description of any reasonably foreseeable risks or discomforts to the participant, including invasion of privacy;

c. A description of any benefits to the participant or to others which may reasonably be expected from the research;

a. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

b. A statement that informs participants of their right not to be a participant in the research

project that is also a teaching exercise;

c. A statement that the participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;

(Page 1 of 3)