SIMPSON
UNIVERSITY

Simpson University Institutional Review Board
General Requirements for Informed Consent

In seeking informed consent the following information shall be provided to each participant. *[45 CFR 46.116]*

1. The fact that the study involves research.

2. The purpose of the research, the expected duration of participation, and the procedures to be followed and identification of any procedures which are experimental.

3. A description of any reasonably foreseeable risks or discomforts to the participant.

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

5. A disclosure of any appropriate alternate procedures or courses of treatment which might be advantageous to the subject.

6. A statement describing the extent to which confidentiality of records that identifies the participant will be maintained.

7. For research involving more than minimal risk, an explanation as to whether any compensation or follow-up medical treatment will be provided if injury occurs and, if so, what that consists of and where further information about it may be obtained.

8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in event of a research-related injury to the subject.

9. A statement that participation is voluntary and that refusal to participate or to continue to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.

10. Where appropriate, one or more of the following elements of information shall also be provide to the participants:

    a) a statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.

    b) a statement that any significant new finding developed during the course of the research which may relate to the participant's willingness to continue participation will be provided.

    c) anticipated circumstances under which participation may be terminated without the participant's consent.

    d) any additional costs to the participant that may result from participation in research.

    e) the consequence of a participant's decision to withdraw from the research and procedures for the orderly termination of participation.

    f) the approximate number of participants in the study.

11. Furthermore, this information shall:

    a) be in language understandable to the participant or the participant's legally authorized representative.

    c) be conveyed under circumstances that all the participant or the participant's legally authorized representative sufficient opportunity to consider whether to agree to participate.

    d) not include exculpatory language through which the participant or the participant's legally authorized representative is led to waive any of the participant's legal rights or release the investigator or university from liability for negligence.