**MODEL OF A STANDARD CONSENT FORM**

Your consent form will be compared against the following model in order to meet federal requirements.

The following model of an Informed Consent Form contains all elements required by law, with instructions to assist you in the development of the consent form of your project.

**CONSENT FORM**

***(YOUR PROJECT TITLE APPEARS HERE)***

**Invitation to Participate:** You are invited to participate in a study of (describe what is to be studied) being conducted by (give names of investigators and their affiliations with SSU and other institutions involved).

**Basis for Subject Selection:** You have been selected because (state reasons why). This statement should help the subject assess the nature and importance of participation. When appropriate, state the approximate number of subjects involved in the study and any criteria for subject exclusion (e.g. pregnancy, age, limitations, health restrictions).

**Overall Purpose of Study:** Give a clear description in simple language of the overall purpose of the research. This should help the subject assess the importance of the study relative to individual values.

**Explanation of Procedures:** If you decide to participate, you will be given the following tests or asked to do the following things: These should include, where appropriate, the following:

1. A description of the study design (e.g., longitudinal, single blind, placebo, quantitative, qualitative).
2. A description of each procedure to be applied to human subjects and how often it will be performed.
3. The identification of the individual(s) who will perform the procedures.
4. A statement of where and when the research will be conducted, and how much time (per session and in total) will be required of the subject.
5. A statement concerning any medications, therapeutic regimens, foods, or other substances that are contraindicated/disallowed either before or during participation in the study.
6. If the research study involves incomplete disclosure or deception, all subjects must be debriefed as soon as possible after participation. The consent form for nondisclosure/deceptive studies should normally contain a statement concerning when and where the debriefing session will be held. If debriefing may be harmful to the subject, the investigator may request a waiver of the debriefing requirement.

**Potential Risks and Discomforts:** Remember that the IRB will make the determination as to whether or not your project involves risks to the human subjects. Risks can be classified generally, with some overlap, as:

1. Physical -- e.g., infection associated with venipuncture or surgery, adverse reactions to drugs, heart attack induced by maximal exercise tests
2. Psychological -- e.g., depression, confusion, feelings of guilt
3. Social -- e.g., invasion of privacy, loss of community standard
4. Legal -- e.g., criminal prosecution, revocation of parole
5. Economic -- e.g., loss of employment, loss of potential monetary gain

Both immediate and later risks of any procedure must be clearly and adequately described, including the probability, severity, average duration, and reversibility of any potential injury.

**Potential Benefits:** Describe direct benefits, if any (e.g., improvement of health status). If there are no direct benefits to the participants, explain the benefits that could result to others from this research (e.g., acquisition of knowledge). It must be stated in the description that the benefits are hoped for (or anticipated), but not guaranteed by the investigator.

**Alternatives to Participation:** Describe alternative treatment, if any, if the prospective subjects are students who would participate in exchange for receipt or academic credit if he/she chooses not to participate. The option(s) must be comparable to research participation in terms of time, effort and educational benefit. This is not the same as "extra credit", which is a compensation for participation.

**Compensation for Participation:** If the subject will receive compensation, describe the amount or nature of the compensation (grade, credits, money, etc.). The nature and amount of compensation must not constitute undue inducement to participate.

**Assurance of Confidentiality:** State that any information obtained that could identify the subject will remain confidential and will be disclosed only with the subject's permission. If the investigator intends to release any information, the consent form must state persons or agency receiving the information, the nature of the information, the purpose of the disclosure, and whether the subject's name will be used as an identifier. When appropriate, the ultimate disposition of data should be described. Confidentiality safeguards must be especially strong where a breach of confidentiality may result in social or economic harm to the subject.

**Statement of Injury or Special Costs:** Describe any special costs to the subjects.

**Withdrawal from the Study:** Your participation is voluntary. You may answer any, all or none of the questions. Refusal to participate carries no penalties. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time.

**Offer to Answer Questions:** You should feel free to ask questions now or at any time during the study. If you have questions, you can contact: (Give your name and phone number and the name and phone number of any co-investigator. For research studies involving more than minimal risk, the home/night phone number of the investigator(s) must be provided.) If you have any questions about the rights of research subjects, contact the SSU Chair of the IRB.

**Consent Statement:**

You are voluntarily making a decision whether or not to participate. Your signature indicates that, having read and understood the information provided above, you have decided to participate. You will be given a copy of this consent form to keep.

**Signature of Subject Date**

**Signature of Witness Signature of Investigator**

(The signature of a witness is required for all research studies involving more than minimal risk. If possible, the witness should be someone who is not involved in the study.)