California University of Pennsylvania Institutional Review Board
Informed Consent Checklist (v021209)

This form MUST accompany all IRB review requests:

Does your research involve ONLY a survey, questionnaire, or interview?
YES—DO NOT complete this form. Complete the Survey/Questionnaire/Interview Consent Checklist instead.
NO—Complete the remainder of this form.

1. **Introduction** (check each)
   [_] (1.1) Is there a statement that the study involves research?
   [_] (1.2) Is there an explanation of the purpose of the research?

2. Is the participant. (check each)
   [_] (2.1) Given an invitation to participate?
   [_] (2.2) Told why he/she was selected.
   [_] (2.3) Told the expected duration of the participation.
   [_] (2.4) Informed that participation is voluntary?
   [_] (2.5) Informed that all records are confidential?
   [_] (2.6) Told that he/she may withdraw from the research at any time without penalty or loss of benefits?
   [_] (2.7) 18 years of age or older? (if not, see Section #9, Special Considerations below)

3. Procedures (check each).
   [_] (3.1) Are the procedures identified and explained?
   [_] (3.2) Are the procedures that are being investigated clearly identified?
   [_] (3.3) Are treatment conditions identified?

4. Risks and discomforts. (check each)
   [_] (4.1) Are foreseeable risks or discomforts identified?
   [_] (4.2) Is the likelihood of any risks or discomforts identified?
   [_] (4.3) Is there a description of the steps that will be taken to minimize any risks or discomforts?
   [_] (4.4) Is there an acknowledgement of potentially unforeseeable risks?
   [_] (4.5) Is the participant informed about what treatment or follow up courses of action are available should there be some physical, emotional, or psychological harm?
   [_] (4.6) Is there a description of the benefits, if any, to the participant or to others that may be reasonably expected from the research and an estimate of the likelihood of these benefits?
   [_] (4.7) Is there a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant?

5. Records and documentation. (check each)
   [_] (5.1) Is there a statement describing how records will be kept confidential?
   [_] (5.2) Is there a statement as to where the records will be kept and that this is a secure location
   [_] (5.3) Is there a statement as to who will have access to the records?

6. For research involving more than minimal risk (check each),

[_] (6.1) Is there an explanation and description of any compensation and other medical or counseling treatments that are available if the participants are injured through participation?
[_] (6.2) Is there a statement where further information can be obtained regarding the treatments?
[_] (6.3) Is there information regarding who to contact in the event of research-related injury?

7. Contacts.(check each)
[_] (7.1) Is the participant given a list of contacts for answers to questions about the research and the participant's rights?
[_] (7.2) Is the principal researcher identified with name and phone number and email address?
[_] (7.3) FOR ALL STUDENTS: Is the faculty advisor's name and contact information provided?

8. General Considerations (check each)
[_] (8.1) Is there a statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information in the informed consent?
[_] (8.2) Are all technical terms fully explained to the participant?
[_] (8.3) Is the informed consent written at a level that the participant can understand?
[_] (8.4) Is there text equivalent to: "Approved by the California University of Pennsylvania Institutional Review Board. This approval is effective nn/nn/nn and expires mm/mm/mm"? (the actual dates will be specified in the approval notice from the IRB)

9. Specific Considerations (check as appropriate)
[_] (9.1) If the participant is or may become pregnant is there a statement that the particular treatment or procedure may involve risks, foreseeable or currently unforeseeable, to the participant or to the embryo or fetus?
[_] (9.2) Is there a statement specifying the circumstances in which the participation may be terminated by the investigator without the participant's consent?
[_] (9.3) Are any costs to the participant clearly spelled out?
[_] (9.4) If the participant desires to withdraw from the research, are procedures for orderly termination spelled out?
[_] (9.5) Is there a statement that the Principal Investigator will inform the participant or any significant new findings developed during the research that may affect them and influence their willingness to continue participation?
[_] (9.6) Is the participant is less than 18 years of age? If so, a parent or guardian must sign the consent form and assent must be obtained from the child
    [_] Is the consent form written in such a manner that it is clear that the parent/guardian is giving permission for their child to participate?
    [_] Is a child assent form being used?
    [_] Does the assent form (if used) clearly indicate that the child can freely refuse to participate or discontinue participation at any time without penalty or coercion?
[_] (9.7) Are all consent and assent forms written at a level that the intended participant can understand? (generally, 8th grade level for adults, age-appropriate for children)