California University of Pennsylvania Institutional Review Board
Survey/Interview/Questionnaire Consent Checklist (v021209)

This form MUST accompany all IRB review requests

Does your research involve ONLY a survey, interview or questionnaire?
YES—Complete this form
NO—You MUST complete the "Informed Consent Checklist"—skip the remainder of this form

Does your survey/interview/questionnaire cover letter or explanatory statement include:

[_] (1) Statement about the general nature of the survey and how the data will be used?

[_] (2) Statement as to who the primary researcher is, including name, phone, and email address?

[_] (3) FOR ALL STUDENTS: Is the faculty advisor's name and contact information provided?

[_] (4) Statement that participation is voluntary?

[_] (5) Statement that participation may be discontinued at any time without penalty and all data discarded?

[_] (6) Statement that the results are confidential?

[_] (7) Statement that results are anonymous?

[_] (8) Statement as to level of risk anticipated or that minimal risk is anticipated? (NOTE: If more than minimal risk is anticipated, a full consent form is required—and the Informed Consent Checklist must be completed)

[_] (9) Statement that returning the survey is an indication of consent to use the data?

[_] (10) Who to contact regarding the project and how to contact this person?

[_] (11) Statement as to where the results will be housed and how maintained? (unless otherwise approved by the IRB, must be a secure location on University premises)

[_] (12) 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)?

[_] (13) FOR ELECTRONIC/WEBSITE SURVEYS: Does the text of the cover letter or explanatory statement appear before any data is requested from the participant?

[_] (14) FOR ELECTONIC/WEBSITE SURVEYS: Can the participant discontinue participation at any point in the process and all data is immediately discarded?

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, interview, or questionnaire?
YES—DO NOT complete this form. You MUST complete the "Survey/Interview/Questionnaire 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)

California University of Pennsylvania Institutional Review Board
Review Request Checklist (v021209)

This form MUST accompany all IRB review requests.
Unless otherwise specified, ALL items must be present in your review request.

Have you:

[_] (1.0) FOR ALL STUDIES: Completed ALL items on the Review Request Form?
Pay particular attention to:

[_] (1.1) Names and email addresses of all investigators

[_] (1.1.1) FOR ALL STUDENTS: use only your CalU email address)

[_] (1.1.2) FOR ALL STUDENTS: Name and email address of your faculty research advisor

[_] (1.2) Project dates (must be in the future—no studies will be approved which have already begun or scheduled to begin before final IRB approval—NO EXCEPTIONS)

[_] (1.3) Answered completely and in detail, the questions in items 2a through 2d?

[_] 2a: NOTE: No studies can have zero risk, the lowest risk is "minimal risk". If more than minimal risk is involved you MUST:

[_] i. Delineate all anticipated risks in detail;

[_] ii. Explain in detail how these risks will be minimized;

[_] iii. Detail the procedures for dealing with adverse outcomes due to these risks.

[_] iv. Cite peer reviewed references in support of your explanation.

[_] 2b. Complete all items.

[_] 2c. Describe informed consent procedures in detail.

[_] 2d. NOTE: to maintain security and confidentiality of data, all study records must be housed in a secure (locked) location ON UNIVERSITY PREMISES. The actual location (department, office, etc.) must be specified in your explanation and be listed on any consent forms or cover letters.

[_] (1.4) Checked all appropriate boxes in Section 3? If participants under the age of 18 years are to be included (regardless of what the study involves) you MUST:

[_] (1.4.1) Obtain informed consent from the parent or guardian—consent forms must be written so that it is clear that the parent/guardian is giving permission for their child to participate.

[_] (1.4.2) Document how you will obtain assent from the child—This must be done in an age-appropriate manner. Regardless of whether the parent/guardian has given permission, a child is completely free to refuse to participate, so the investigator must document how the child indicated agreement to participate ("assent").

[_] (1.5) Included all grant information in section 5?

[_] (1.6) Included ALL signatures?

[_] (2.0) FOR STUDIES INVOLVING MORE THAN JUST SURVEYS, INTERVIEWS, OR QUESTIONNAIRES:

[_] (2.1) Attached a copy of all consent form(s)?

[_] (2.2) FOR STUDIES INVOLVING INDIVIDUALS LESS THAN 18 YEARS OF AGE: attached a copy of all assent forms (if such a form is used)?

[_] (2.3) Completed and attached a copy of the Consent Form Checklist? (as appropriate—see that checklist for instructions)

[_] (3.0) FOR STUDIES INVOLVING ONLY SURVEYS, INTERVIEWS, OR QUESTIONNAIRES:

[_] (3.1) Attached a copy of the cover letter/information sheet?

[_] (3.2) Completed and attached a copy of the Survey/Interview/Questionnaire Consent Checklist? (see that checklist for instructions)

[_] (3.3) Attached a copy of the actual survey, interview, or questionnaire questions in their final form?

[_] (4.0) FOR ALL STUDENTS: Has your faculty research advisor:

[_] (4.1) Thoroughly reviewed and approved your study?

[_] (4.2) Thoroughly reviewed and approved your IRB paperwork? including:

[_] (4.2.1) Review request form,

[_] (4.2.2) All consent forms, (if used)

[_] (4.2.3) All assent forms (if used)

[_] (4.2.4) All Survey/Interview/Questionnaire cover letters (if used)

[_] (4.2.5) All checklists

[_] (4.3) IMPORTANT NOTE: Your advisor's signature on the review request form indicates that they have thoroughly reviewed your proposal and verified that it meets all IRB and University requirements.

[_] (5.0) Have you retained a copy of all submitted documentation for your records?