

UCSD Human Research Protection Program Project Review Worksheet
Social and Behavioral Research Studies

Section 1: Project Characteristics

HRPP number:		PI last name:		Reviewer last name:		Date:	
Project Title:							
Characteristics: (check all that apply)	<input type="checkbox"/> New	<input type="checkbox"/> Funded	<input type="checkbox"/> Federal or Nonprofit Sponsor	<input type="checkbox"/> Minimal Risk			
	<input type="checkbox"/> Renewal	<input type="checkbox"/> Unfunded	<input type="checkbox"/> Commercial Sponsor	<input type="checkbox"/> Significant (more than minimal) Risk			

Section 2: Research Plan Checklist

Yes	No*	N/A	Topic or Review Criterion
			If this is a resubmission of a previously approved study, or a Continuing Review, has Progress to Date been adequately reported? (Facesheets 3, Research Plan 7)
			Study design is adequate to address research question(s); rationale for the number of subjects is justified; inclusion/exclusion criteria appropriate; and study endpoints well defined. (Research Plan 8, 9)
			The Risks are well described and if there are Special Risks (e.g., risk to subject reputation, deception, incomplete disclosure, psychological intervention), there is sufficient rationale provided to justify these risks. Include evaluation of physical, psychological, social, legal, and economic risks (Research Plan 14)
			Risks to subjects are minimized: using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes. Additional information to consider includes whether there is/are resources necessary to protect subjects; adequate time for the investigators to conduct and complete the research; adequate number of qualified staff; adequate facilities in which to conduct the research; access to population that will allow recruitment of the necessary number of subjects; and medical or psychosocial resources available that subjects may need as a consequence of the research. (45 CFR 46.111 (1)) (Research Plan 15)
			When appropriate, the Research Plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111 (a)(6)) (Research Plan 8, 15)
			If subjects are vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, or economically and educationally disadvantaged persons, additional safeguards must be included in study to protect rights and welfare of these subjects. (45 CFR 46.111 (b)) (Facesheets 3, Research Plan 9, 10, 15)
			If applicable, have surveys and questionnaires been provided and reviewed? (Research Plan 8)
			Selection of subjects is equitable. Take into account the purposes of the research and the setting in which the research will be conducted and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (45 CFR 46.111 (3)) (Research Plan 8, 9, 10, 15)
			Procedures for the orderly termination of a volunteer's participation are adequately described. Information provided to subjects should include disclosures that data collected about the participant up to the point of withdrawal will remain part of the study. Procedures for withdrawal of a participant from a study should also address whether the participant wishes to provide continued follow-up and further data collection. The PI should distinguish between study-related interventions and continued follow-up of associated clinical outcome information. (Research Plan 15)
			Have recruitment materials , ads, and participant information (letters, etc.) been provided and reviewed? (Research Plan 10)
			Are incentives for participation appropriate and not considered undue inducements? (Research Plan 11)
			Informed consent will be sought from each prospective subject (45 CFR 46.111 (4)) or the subject's legally authorized representative. If not, are all required elements addressed for waiver of consent, documented consent and/or HIPAA authorization present? (Facesheets 3, Research Plan 8, 12)
			Is the consent/assent process described including the circumstances under which consent/assent will be obtained; who will seek consent/assent; procedures for minimizing the possibility of coercion and undue influence; allowing for sufficient time to consider enrolling; enrollment of non-English speaking participants? (Research Plan 12)
			Consent is appropriately documented (45 CFR 46.111 (5)) (Research Plan 12)
			Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, you should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). You should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (45 CFR 46.111 (2)) (Research Plan 14, 16, 17)
			There is adequate management of information relevant to the protection of subjects in regards to unanticipated problems involving risks to subjects or others; interim results; and protocol modifications. (Research Plan 14, 15)
			If there is no direct benefit to the participants, are the benefits to future patients or knowledge to be gained described? (If there is direct benefit , answer "N/A") (Research Plan 6)
			There are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. (45 CFR 46.111 (7)) (Research Plan 8, 10, 12, 15)
			Are costs to subjects including costs due to injury/illness described? (Research Plan 19)
			Are the scientific training/qualifications/credentialing and privileges of PI and research staff described and adequate? (Research Plan 18)

*For items checked "No", make an entry in the *Issues Needing Clarification or Revision* section on back

Section 3: Informed Consent Checklist

Yes	No*	N/A	Consent Element
			A clear statement that the study is research
			All of the research purposes (i.e., protocol objectives) are clearly stated
			For sponsored studies, the sponsor is identified
			Description of how, why, and how many prospective volunteers will be selected
			Expected duration of the volunteer's involvement
			Procedures or treatments to be done and explanation which procedure(s) or treatment(s) are experimental
			Where collaborators will receive data or samples , this is clearly stated
			Reasonably foreseeable discomforts and risks
			Statement that the treatments or procedures "may involve risks that are currently unforeseeable. "
			For studies involving placebo , there is adequate information on this in procedure and risk sections of the consent
			Reasonably expected benefits to participant and others
			Financial considerations: extra costs of, or compensation for participation
			Availability of medical care and any other compensation for research-related injury
			Statement of whom a volunteer should contact for injury or adverse event
			Contact information for HRPP office for questions about participant rights
			Statement of who will answer questions about the research itself
			Alternatives to participation
			Non-coercion disclaimer e.g., Participation in research is entirely voluntary
			Description of how confidentiality will be maintained
			Procedures for orderly termination of a volunteer's participation
			Consequences of a volunteer's withdrawal from the research
			Description of circumstances where researcher may terminate a volunteer's participation without their consent
			Plan to inform volunteers of significant research findings relevant to their continued participation
			Conflict of Interest: Moore clause needed and present in the consent?
			The consent does not contain any exculpatory language that holds harmless the sponsor or researcher
			Other elements a reasonable person would want to know

*For items checked "No", make an entry the *Informed Consent Changes Needed* section on back

Section 4: Suggested Review Presentation Format

HRPP number:		PI last name:		Reviewer last name:		Date:	
1. Note relevant Project Characteristics from Section 1							
2. Background and Significance:							
3. Specific Aim(s) of the Project:							
4. Synopsis of Research Plan:							
5. Research Plan Issues needing Clarification or Revision:							
6. Informed Consent Changes Needed:							
7. Overall Recommendation: <input type="checkbox"/> Approve <input type="checkbox"/> Approve Pending Revision <input type="checkbox"/> Defer <input type="checkbox"/> Disapprove							