

UCSD Human Research Protections Program Project Review Worksheet

Section 1: Project Characteristics			
HRPP number:		PI last name:	
		Reviewer last name:	
Project Title:			
Characteristics: (check all that apply)	<input type="checkbox"/> New <input type="checkbox"/> Renewal	<input type="checkbox"/> Funded <input type="checkbox"/> Unfunded	<input type="checkbox"/> Federal or Nonprofit Sponsor <input type="checkbox"/> Commercial Sponsor <input type="checkbox"/> Minimal Risk <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 continuation of a previously approved study (resubmission), has <b>progress-to-date</b> been adequately reported?
			Are there <b>special risks</b> (e.g., placebos, challenge studies, radiation exposure, deviation from standard of care) and if so, is sufficient rationale provided to justify these risks? Include evaluation of physical, psychological, social and economic risks.
			Do the expected <b>benefits</b> outweigh the expected <b>risks</b> ?
			If there is <b>no direct benefit</b> to the participants, are the benefits to future patients or knowledge to be gained mentioned?
			Is <b>subject selection</b> equitable?
			Have conditions for " <b>special classes of subjects</b> " (i.e., children, cognitively impaired, prisoners, etc.) been met?
			If this is a NIH funded study or a clinical trial is there a <b>Data and Safety Monitoring plan</b> and/or formal DSMB?
			If this study involves a <b>device</b> that is not FDA approved, has the Investigational Device Exemption (IDE) or 510(k) reference been provided?
			If this study involves a <b>drug or biologic</b> that is not FDA approved, is there an Investigational New Drug (IND) number provided?
			Does the study involving <b>DNA testing</b> , or other form of genetic analysis? If so, have the IRB DNA Guidelines been followed?
			Are the scientific <b>training/qualifications/credentialing</b> and privileges of PI and research staff outlined and adequate?
			If applicable, have <b>surveys and questionnaires</b> been provided and reviewed?
			Are <b>incentives for participation</b> appropriate & not overly coercive?
			Are there any exemptions/ <b>waiver of consent</b> /oral consent or waiver of any other elements that require special attention?
			Has participant's <b>capacity to consent been addressed</b> ? Is there sufficient caregiver/guardian information provided?
			Have <b>recruitment materials</b> , ads, and subject information (letters, etc.) been provided and reviewed?
			Does the research plan include adequate safeguards for <b>privacy &amp; confidentiality</b> ?

\*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 <b>research</b>
			All of the the research <b>purposes</b> (ie., protocol objectives) are clearly stated
			Description of how, why, and how many prospective volunteers will be <b>selected</b>
			Expected <b>duration</b> of the volunteer's involvement
			<b>Procedures or treatments</b> to be done and explanation which procedure(s) or treatment(s) are <b>experimental</b>
			Reasonably expected <b>benefits</b> to volunteer and others
			Reasonably foreseeable discomforts and <b>risks</b>
			Statement that the treatments or procedures "may involve <b>risks that are currently unforeseeable.</b> "
			For studies involving <b>placebo</b> , there is adequate information on this in procedure and risk sections of the consent
			<b>Alternatives</b> to participation
			Procedures for <b>orderly termination</b> of a volunteer's participation
			Consequences of a volunteer's <b>withdrawal</b> from the research
			Description of circumstances where researcher may <b>terminate a volunteer's participation</b> without their consent
			Plan to <b>inform</b> volunteers of significant research findings relevant to their continued participation
			Availability of medical care and any other compensation for <b>research-related injury</b>
			Statement of whom a volunteer should <b>contact for injury or adverse event</b>
			Statement of who will <b>answer questions</b> about the research itself
			Description of how <b>confidentiality</b> will be maintained.
			Statement of who <b>will have access</b> to research records (for FDA trials, includes FDA)
			Contact information for HRPP office for <b>questions about volunteer's rights</b>
			Financial considerations: <b>extra costs of, or compensation for</b> , participation
			<b>Non-coercion disclaimer.</b> E.G., "Participation in research is entirely voluntary.
			<b>Conflict of Interest:</b> Moore clause needed and present in the consent?
			<b>Other elements</b> a reasonable person would want to know
			For sponsored studies, the <b>sponsor is identified.</b> ?
			Where collaborators will <b>receive data or samples</b> , this is clearly stated
			Where applicable, <b>guardian/caregiver/study contact consents</b> are provided
			Validated <b>translations of consent</b> have been provided
			The consent does not contain any <b>exculpatory language</b> that holds harmless the sponsor or researcher

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

### Section 4: Suggested Review Presentation Format

HRPP number:		PI last name:		Reviewer last name:		Date:	
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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:  Approve  Approve Pending Revision  Defer  Disapprove