UCSD Human Research Protection Program Project Review Worksheet
Biomedical Research Studies

Section 1: Project Characteristics

HRPP number:		PI last name:		Reviewer last name:		Date:	
Project Title:							
Characteristics: (check all that apply)	☐ New ☐ Renewal	☐ Funded ☐ Federal or Nonprofit Sponsor ☐ Unfunded ☐ Commercial Sponsor		☐ Minimal Risk ☐ 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 8)
☐	☐	☐	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 9,10)
☐	☐	☐	Are the **Risks** well described and are there **Special Risks?** (e.g., placebos, challenge studies, radiation exposure, deviation from standard of care) and is sufficient rationale provided to justify these risks? Include evaluation of physical, psychological, social, legal, and economic risks.(Research Plan 8, 14, 15, 18)
☐	☐	☐	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 CRF 46.111 (1)) (Research Plan 9,10,14,15, 21)
☐	☐	☐	When appropriate, the Research Plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111 (6)) (Facesheets 3, Research Plan 9, 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, 11, 12, 15, 16, 20, 21, 30)
☐	☐	☐	If applicable, have **surveys and questionnaires** been provided and reviewed? (Research Plan 9)
☐	☐	☐	Are there **research-related** procedures/risks associated with **radiation exposure** to participants? (Facesheets 4, Research Plan 9, 14)
☐	☐	☐	For studies involving **DNA** genotyping or other form of genetic analysis, have the IRB DNA Guidelines been followed? (Facesheets 3, Research Plan 9, 12)
☐	☐	☐	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 9, 10, 11)
☐	☐	☐	Procedures for the orderly termination of a volunteer's participation described including data collected about the participant to the point of withdrawal remains part of the study; whether participant withdrawing wishes to provide continued follow-up and further data collection (distinguished between study-related interventions and continued follow-up of associated clinical outcome information). (Research Plan 9, 12, 15)
☐	☐	☐	If decisionally impaired subjects will be recruited, has **decisional capacity** assessment and use of **surrogate consent** been addressed? (Facesheets 3, Research Plan 10, 11, 30)
☐	☐	☐	Have **recruitment materials**, ads, and participant information (letters, etc.) been provided and reviewed? (Research Plan 11)
☐	☐	☐	Are **incentives for participation** appropriate and not considered undue inducements? (Research Plan 11, 20)
☐	☐	☐	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 12, 30)
☐	☐	☐	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, 16)
☐	☐	☐	Consent is appropriately documented (45 CFR 46.111 (5)) (Research Plan 12, 30)
☐	☐	☐	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 9, 14, 16, 17, 18)
☐	☐	☐	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)
☐	☐	☐	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 17, 18)
☐	☐	☐	There are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. (45 CFR 46.111 (7)) (Research Plan 16)
☐	☐	☐	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 21)
☐	☐	☐	If this study involves a **device** that is not FDA-approved (or it involves a non-approved use of an approved device), has the Investigational Device Exemption (IDE), 510(k) or Non-Significant Risk Device reference been provided? (Facesheets 4, Research Plan 25)
☐	☐	☐	If this study involves a **drug or biologic** that is not FDA-approved (or an off-label use of an approved drug), is an Investigational New Drug (IND) number provided? (Facesheets 4, Research Plan 25)

*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: ☐ Approve ☐ Approve Pending Revision ☐ Defer ☐ Disapprove