

IRB Protocol #	PI	Reviewer	Date
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INITIAL APPLICATION REVIEW

Y/N/NA

- Cover Letter describing reason for submission, areas of special concern, list of attached documents, and a brief summary of difficult ethical issues or special considerations for review, or requests for special handling, as appropriate
- Application Facesheets with all sections completed and signed by the Principal Investigator (and the signature of the Faculty Advisor/Department Chair must be provided before final approval can be granted).
- PI eligible to be PI for UCSD project
- PI UCSD IRB/HRPP CITI training is complete and current
- UCSD Research Plan with all 21 items completed
- Master Protocol (or “full” or “multicenter” protocol)

- IRB Application Informational Supplements completed
- Approval documentation included for studies involving non-UCSD Affiliated Sites

- Recruitment materials
 - Copies of ads, notices or flyers
 - Telephone script/oral consent used for recruiting
 - Pamphlets/Brochures
- Consent/Permission/Assent Documents
 - Consent/Permission form(s) (written for participant, parents or legal guardian, surrogate, etc.)
 - Assent form(s) for children and/or adolescents, if applicable
 - Informational sheet(s) for participants, if applicable
 - Oral consent script(s), if applicable
- Additional materials
 - Self-Certification of Surrogate Decision makers for Potential Subject’s Participation
 - Assessment materials to evaluate decisional capacity
 - Questionnaires and survey instruments for any that are not standardized/validated
 - For expedited protocols, data collection sheet
 - Other materials, as appropriate