

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
- Application Face Sheet with all sections completed including of the signature of the Principal Investigator (the signature of the Department Chair and/or VA Service Chief must be provided before final approval can be granted). If IND, IDE or 510(k) are associated with the study, appropriate number(s) must be provided.
- Completed "VA Receipt of Review Request" form
- UCSD/VA Research Plan with all 28 items completed (if UCSD/Rady Children's Hospital-San Diego, all 29 items completed)
- Sponsor's Master Protocol (or "full" or "multicenter" protocol)
- Investigator's Brochure
- Investigational Drug Fact Sheet
- Justification for Non-Significant Risk Determination for an Investigational Device
- Copy of Determination Letter from FDA regarding device if IDE number not provided
- IRB Application Informational Supplements completed
 - IRB approval documentation included for studies involving non-UCSD or non-VASDHS Affiliated Sites, unless clinical trial agreement with sponsor is in place.
- Recruitment materials
 - Copies of ads, notices or flyers
 - Telephone script/oral consent used for recruiting
 - Pamphlets/Brochures
- Consent/Assent Documents, dated, paginated and labeled in the footer
 - Consent form(s) (written, for participant, parents or legal guardian, surrogate, etc.)
 - Assent form(s) for children and/or adolescents
 - Informational sheet(s) for participants, if applicable
 - Oral consent script(s), if applicable
- Addition materials
 - Questionnaires and survey instruments, if any that are not standardized/validated
 - For expedited protocols, data collection sheet

Incomplete

Ready for review