IRB Protocol #	**PI**	**Reviewer**	**Date**

RAPID-CYCLE REVIEW

(All must be "Y" to qualify)

Y/N

☐☐ The application is considered complete. That is, the application includes signed Application Facesheets, Master Protocol, Investigator Brochure, Research Plan, consent document(s), and other study documents, as appropriate.

☐☐ The project is a "clinical trial" according to the FDA definition of a clinical trial[1].

☐☐ The project is a Phase IIb, Phase III, or Phase IV clinical drug trial.

☐☐ The project is industry-sponsored but not PI-initiated.

☐☐ The project is being conducted under a clinical trial agreement directly between a industry sponsor and UCSD (that is, it does not require a contract with another entity, such as a non-profit, academic institution, or federal or state funding agency) where the agreement is being negotiated through OCTA.

☐☐ The project has a DSMB or DSMC in place.

[1]FDA Definition of a Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms clinical study, clinical trail, and clinical investigation are deemed to be synonymous for this purpose.