UCSD INSTITUTIONAL REVIEW BOARD, HUMAN RESEARCH PROTECTIONS PROGRAM

BIOMEDICAL INITIAL SUBMISSION SCREENING CHECKLIST

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

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 Department Chair must be provided before final approval can be granted). If IND, IDE, or 510(k) is associated with the study, appropriate number(s) must be provided.

☐☐☐ PI eligible to be PI for UCSD project

☐☐☐ PI UCSD IRB/HRPP CITI training is complete and current

☐☐☐ UCSD Research Plan with all 30 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 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

- ☐ Completed UCSD HIPAA authorization
- ☐ 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