

Table A: California Human Stem Cell Research Oversight Requirements

Type of Research	SCRO Committee Review & Approval	IRB* Review & Approval
Covered research involving the procurement of human oocytes	Yes	Yes
Covered research involving the use of human oocytes	Yes	Yes, if human and/or non-human animal subjects involved
Covered research involving the use of human embryos	Yes	Yes, if human and/or non-human animal subjects involved
Covered research with the aim to derive or create a covered stem cell line	Yes	Yes, if human and/or non-human animal subjects involved
Purely <i>in vitro</i> covered research	Only written notification to SCRO Committee required	No
Covered research introducing cells from or differentiated from covered stem cell lines into non-human animals	Yes	Yes
Covered research introducing neural-progenitor cells into the brain of non-human animals	Yes	Yes
Clinical trial involving the use of covered cells (includes transfer of non-autologous neural-progenitor stem cells to human central nervous system)	Yes	Yes†
Research involving only human adult stem cells	Only SCRO Committee review required	Yes, if human and/or non-human animal subjects involved
Medical research (other than covered research) involving assisted oocyte production or alternative method of human oocyte retrieval	No	Yes

SCRO Committee: Stem Cell Research Oversight Committee.

Covered stem cell line: a culture-derived, human pluripotent stem cell population that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm.

Covered research: research that derives a covered stem cell line or that uses covered cells.

* This includes Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), and any other required institutional committee review.

† IRBs should establish a Data Safety Monitoring Board to periodically review trial outcomes and safety, as well as provide a monitoring plan for the trial.

NOTE: This table summarizes the oversight requirements in the CDPH Guidelines for Human Stem Cell Research.