

Comparison of CDPH Guidelines and CIRM Regulations

<u>CDPH Guidelines for HSCR</u>	<u>CIRM Regulations</u>	<u>Differences</u>
1. §3(e) Breeding any animal into which stem cells from a human pluripotent stem cell line have been introduced	1. §100030(e)- Breeding any animal into which <u>covered</u> stem cells from a covered stem cell line have been introduced <u>such that they could contribute to the germ line.</u>	1. CIRM regulation added the condition of contribution to the germ line.
2. §5(e)- Research introducing human pluripotent cells or cells differentiated from human pluripotent stem cell lines into non-human animals, or introducing neural-progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO Committee review and approval in writing.	2. §100070(e)- <u>The introduction of covered stem cells into nonhuman mammalian blastocysts or fetuses or introducing human neural progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. Studies involving postnatal animals performed pursuant to a FDA Investigational New Drug (IND) or Device application are exempt from SCRO committee review and approval. CIRM funded research introducing covered stem cell lines into non-human animals or introducing neural progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing.</u>	2. CIRM regulations allow exemptions from SCRO committee review and approval for studies performed pursuant to a FDA IND or Device application CIRM language of “covered stem cells” vs. CDPH “human pluripotent cells or cells differentiated from human pluripotent cell lines”