

Comparison of CDPH Guidelines and CIRM Regulations

CDPH Guidelines for HSCR

1. §3(e) Breeding any animal into which stem cells from a human pluripotent stem cell line have been introduced
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.

CIRM Regulations

1. §100030(e)- Breeding any animal into which covered stem cells ~~from a covered stem cell line~~ have been introduced such that they could contribute to the germ line.
2. §100070(e)-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.

Differences

1. CIRM regulation added the condition of contribution to the germ line.
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”