



MEMORANDUM

TO: CIRM Standards Working Group

FROM: Geoff Lomax, Associate Director, Medical Affairs & Policy

RE: February 9, 2024 SWG Meeting

DATE: January 2, 2023

---

**Introduction:**

The California Institute for Regenerative Medicine (CIRM) will convene the Scientific and Medical Accountability Standards Working Group (Standards Working Group or SWG) to consider oversight considerations for research protocols involving embryo model systems. The meeting date is Friday February 9, 2024, for a hybrid meeting at the Asilomar Conference Grounds in Pacific Grove.

**Embryo Model Systems:**

Embryo models are organized three-dimensional structures created in a laboratory dish with stem cells. The models mimic the developmental processes that occur in early human embryos. Use of these models allows modeling of the early stages of development that occur in the first few weeks of pregnancy. They can facilitate understanding of early pregnancy loss and placental failure, and help researchers gain basic knowledge of the early developmental origins of congenital defects in the heart, nervous system, and other organs.

The review, approval, and oversight of protocols involving hPSC-derived embryo models is an ongoing subject of regulatory policy deliberations.<sup>1,2,3</sup> CIRM research is governed by comprehensive medical and ethical standards codified in the CIRM regulations<sup>4</sup> generally aligned with those adopted by the National Academy of Sciences. These standards include the review and ongoing oversight of research protocols.

*SWG Charge:*

---

<sup>1</sup> <https://www.nationalacademies.org/event/01-17-2020/examining-the-state-of-the-science-of-mammalian-embryo-model-systems-a-workshop>

<sup>2</sup> <https://www.isscr.org/isscr-news/isscr-statement-on-new-research-with-embryo-models>

<sup>3</sup> [https://www.cell.com/cell/fulltext/S0092-8674\(23\)00807-3](https://www.cell.com/cell/fulltext/S0092-8674(23)00807-3)

<sup>4</sup> [https://www.cirm.ca.gov/wp-content/uploads/archive/files/funding\\_page/100070\\_SCRO%20Committee%20Review%20and%20Notification\\_MES\\_18.03.02.pdf](https://www.cirm.ca.gov/wp-content/uploads/archive/files/funding_page/100070_SCRO%20Committee%20Review%20and%20Notification_MES_18.03.02.pdf)

Consider the use of hPSC-derived model systems in research. Review CIRM's standards involving the oversight of research protocols in light of advances in hPSC-derived embryo models. Consider whether further guidance is warranted.