

§ 100082. Exception for Covered Stem Cell Lines

(a) A covered stem cell line that is not considered “acceptably derived” under Title 17, California Code of Regulations, section 100080, may be used in CIRM-funded research if the ICOC determines in a public meeting that use of the covered stem cell line in CIRM-funded research will advance CIRM’s mission. Factors to be considered by the ICOC in determining whether use of the covered stem cell line in CIRM-funded research will advance CIRM’s mission include, but are not limited to, the following:

(1) the strength of the scientific or clinical rationale for use of the covered stem cell line, and how use of the covered stem cell line will advance CIRM’s mission;

(2) the nature and adequacy of the consents given by the donors of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line;

(3) the nature of the valuable consideration provided to the donors of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line in exchange for their donation, including reimbursement for the cost of storage prior to donation;

(4) whether the donation of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line was overseen by an IRB or equivalent; and

(5) whether the donation of human gametes, embryos, somatic cells or tissue used to create the covered stem cell line was consistent with “best practices” at the time of donation.

(b) The President of CIRM may request an exception by presenting a proposal to the ICOC in public session describing how use of the covered stem cell line will advance CIRM’s mission based on the factors identified in subdivision (a).

(c) A CIRM grantee or potential grantee may request an exception by submitting a petition that includes the information specified in section 100081(a)(1)-(8) and that describes how use of the covered stem cell line will advance CIRM’s mission based on the factors identified in subdivision (a)

(d) The ICOC must consider the merits of a request from the President or a petitioner in open session, and must vote to grant or deny the request or petition in open session. Members of the ICOC may consider confidential and proprietary information relating to the request or petition in closed session before taking action on the request or petition.