Summary of Revisions to the
CDPH Guidelines for Human Stem Cell Research

Version July 2, 2007

First version of the CDPH Guidelines for Human Stem Cell Research is finalized and published.

Version October 1, 2008

Technical amendments to Section 11(c) and (d) indicate SCRO Committees need only report on human embryonic stem cell research projects not all covered research projects.

Version September 10, 2009

At the time the CDPH Guidelines for Human Stem Cell Research were first released in July 2007, induced pluripotent stem cell (iPSC) research had yet to develop sustainable pluripotent stem cell lines derived from human somatic cells. Within a year, the rapid progress of iPSC research led to the derivation of pluripotent stem cells lines from human somatic cells that were self-renewing and sustainable in culture. As such, iPSC lines fell under the Guidelines "covered stem cell line" definition and the corresponding requirements for informed consent and SCRO Committee review.

Somatic cells have long been used in research with ethically appropriate consent and institutional review. The added protections for the ethically sensitive research materials used in hESC research (i.e. human oocytes and embryos) were not intended to apply to somatic cells. In an effort to distinguish between somatic cells and hESCs, the September 2009 version of the Guidelines has: 1) a new definition of "covered stem cell line"; 2) additional criteria for "acceptable research materials"; and 3) identifies under which circumstances research using iPSCs will require SCRO Committee review, such as when human pluripotent stem cells are introduced into non-human animals.

Section 6(a)(2) was revised to allow for the use of human gametes and embryos created for reproductive purposes from gamete donors that received valuable consideration.

Version December 2011

Section 2(d) was revised to clarify the definition of "covered research".

Section 5(b) was revised to include the creation of embryos as requiring SCRO Committee review and approval. This revision made the Guidelines more consistent with CIRM regulation Section 100070(c).

Note: Refer to CDPH Human Stem Cell Research Advisory Committee meeting archives for meeting minutes of the revisions process and Guidelines documents containing revisions in track changes at: www.cdph.ca.gov/HSCR

Section 5(d)(2) and 5(f)(2) were revised to be consistent with changes made to the previous version of the Guidelines that removed oversight of iPSC research except in a few instances.

Section 10(b) and 10(b)(1) were revised to reinforce the amended definition of "covered research", which excludes iPSC research except in a few instances.

Version August 2017

Section 4(a) was revised to remove the prohibition of appointment or remuneration as part of the qualification for the SCRO non-scientist member of the public. This revision is intended to allow the possibility of stipends, which would be appropriately close to the actual expense incurred by the member for serving on the committee. This also distinguishes appointment at an institution as not prohibited.

Section 5(d) was deleted to remove the requirement of SCRO Committees to review all clinical trials involving the use of human pluripotent stem cells or cells derived from human pluripotent stem cells. However, Section 9 of the Guidelines will remain to require SCRO review of clinical trials involving the use of covered cell lines or cells.

Section 6(a)(1) was revised to include the Australian National Health and Medical Research Council as a recognized authority.

Section 10(b)(2) was revised to clarify that donors must be given the opportunity to impose restrictions on future uses of donated materials during informed consent.

Version July 2018

Section 3(e) was revised to "Breeding any animal into which stem cells from a human pluripotent stem cell line have been introduced *such that they could contribute to the germ line.*"

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