

## Proposed Amendments to CDPH Guidelines for Human Stem Cell Research #2

Change section 6.

To be acceptably derived, the covered cell line must meet one of two standards:

A. They have been derived under the following conditions:

- (1) Donors of gametes, embryos, somatic cells or human tissue gave voluntary and informed consent.
- (2) Donors of gametes, embryos, somatic cells or human tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as determined by an IRB.
- (3) A person may not knowingly, for valuable consideration, purchase or sell gametes, embryos, somatic cells, or human tissue for research purposes. This provision does not prohibit reimbursement for permissible expenditures as approved by a SCRO Committee or IRB, or permissible expenses as determined by an IRB. “Permissible expenditures” include reasonable payment for the removal, processing, disposal, preservation, quality control, transportation of materials, and storage of oocytes or embryos necessary, and reasonable costs directly incurred as a result of persons, not including human subjects or donors, providing gametes, embryos, somatic cells, or human tissue for research purposes.
- (4) Donation of gametes, embryos, somatic cells or human tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent).
- (5) Individuals who consented to donate stored gametes, embryos, somatic cells or human tissue were not reimbursed for the cost of storage prior to the decision to donate.

B. A covered cell line that fails to meet the standards in A, nonetheless is approved by a SCRO on the following grounds. A SCRO has determined that the covered cell line is a “permissible line”, and has also determined that there is sufficient scientific rationale for the need to use the line, though it fails to meet some of the standards set in A. This should include establishing that the proposed research can not be reasonably carried out with existing covered lines that do meet the standards set in A.

A “permissible” line is one that has been approved by an “authorized authority” or in the judgment of a SCRO met the ethical guidelines and standards for voluntary informed consent and oversight (such as those issued by NIH, ASRM, or NBAC) at the time that the line was created.

To be recognized by an authorized authority the stem cell line must:

- (i) Be approved by the National Institutes of Health; or
- (ii) Be deposited in the United Kingdom Stem Cell Bank; or
- (iii) Be derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority; or
- (iv) Be derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research under an application approved by the National Stem Cell Oversight Committee; or

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- (v) Be derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells; or
- (vi) Have been approved by CIRM under the petition process described in section 100081.