

**Addendum - Guidelines for Human Stem Cell Research September 10, 2009 Version**

At the time the California Department of Public Health 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.