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Using Stem Cell Lines

hESC Lines Approved for Use at UCSF

Using Outside Cell Lines

hESC Lines Approved for Use at UCSF

Formerly approved hESC lines will be phased out: Since July 2009, the National Institutes of Health (NIH) ^[1] has begun to re-evaluate and re-approve human embryonic stem cell (hESC) lines for federal funding. Many of the hESC lines approved by NIH in 2001 will not meet the new standards. Both the California Institute of Regenerative Medicine (CIRM) ^[2] and UCSF's GESCR are also modifying their guidelines for approving hESC lines.

Researchers using lines approved by NIH before July 2009 may need to switch to other, more recently approved lines for future or ongoing work. Neither NIH nor CIRM will provide further funding for research using older lines that do not meet the new guidelines, and GESCR may not permit long-term use of these lines at UCSF.

What will happen with the hESC stem cell lines NIH approved in 2001?

hESC lines that were approved by NIH in 2001 will not be eligible for additional NIH funding unless they are approved under the new process. Many of these older hESC lines have not been submitted for NIH approval and are thought not to meet the new NIH guidelines. At this time, the NIH does not plan to "grandfather" any of the old lines onto the current registry.

It is expected that many new hESC lines will be approved and added to the new registry. At present, however, many of the new lines have restricted uses that must be observed.

What if I have CIRM Funding?

The CIRM permits hESC lines on the new NIH Stem Cell Registry [3] to be used in CIRM-funded research (see CIRM statement) [4], as well as hESC lines certified on their own list of Acceptably Derived Embryonic Stem Cells [5]. CIRM may also fund use of lines approved by other organizations with their own consistently applied standards (such as stem cell review panels in the United Kingdom).

Which hESC lines will GESCR allow me to use?

GESCR now will deem hESC lines acceptable for use at UCSF if they are on the new NIH Stem Cell Registry [3]* or if they have been approved for funding by CIRM. Such lines may be used at UCSF even if the individual project is not funded by NIH or CIRM. GESCR also may independently review and approve hESC lines (for example, lines derived at UCSF with GESCR approval).

* Some of the hESC lines on the NIH Registry have restrictions placed on their use. GESCR will honor these restrictions. Each hESC line on the NIH Registry has a ?see details? notation. The restrictions are linked to this notation.

What if I'm currently using cell lines that are not on the new approval lists?

If you are currently using hESC lines that were approved in 2001 but have not been approved under the new NIH guidelines and have not otherwise been approved by CIRM or GESCR, GESCR asks that you provide a plan to transition to a UCSF-acceptable line. This plan should be submitted with your next protocol renewal. GESCR will allow the use of the older lines for the duration of your current grant, but will not approve protocols using these lines after your grant has expired.

You should consult the NIH and CIRM Program Officers for their standards for transitioning to hESC lines currently eligible for their funding.

Has GESCR relaxed its requirements?

GESCR acknowledges that the current NIH hESC guidelines differ from previous GESCR/UCSF policies. The NIH does not require consent from third-party gamete donors for hESC derivation (when applicable), only consent of the couples donating the embryos. Though GESCR remains committed to protecting the gamete donors' interests and wishes, the Committee has agreed to accept the use of approved stem cell lines listed on the new NIH Stem Cell Registry [3] and/or approved by CIRM [6]. Please note that many of the new lines have restricted uses that must be observed.

The GESCR Committee will send updates to stem cell researchers as new regulatory information becomes available.

Using Outside Cell Lines

What is the NIH Registry?

The NIH Human Embryonic Stem Cell Registry ^[7] is a list of stem cell lines that meet the eligibility criteria for federally funded research.

Are all of the cell lines on the NIH Human Embryonic Stem Cell Registry de-identified?

Yes. However, because of California law, GESCR review and approval is still required for research using the NIH Registry cell lines.

How do I obtain Registry materials from outside UCSF?

The Industry Contract Division ^[8] (ICD) of the Office of Sponsored Research is responsible for negotiating Material Transfer Agreements ^[9] (MTAs) for all types of proprietary research materials, including Registry materials from outside organizations for use by UCSF investigators. Investigators who want to receive Registry materials from an outside organization must complete and submit an MTA Request Form ^[9].

Are researchers required to confirm the original consent process?

It is important to respect donors' wishes, whether they donate embryos no longer needed for assisted reproduction or donate gametes that are used to create embryos.

Generally researchers are not expected to verify IRB review and adequate consent when they receive commercially available de-identified cell lines. For almost all other human tissue received for research purposes, the researchers should receive written assurance from the source providing the tissue/cells that the protocol for tissue collection received IRB review or formal exemption. At UCSF, investigators should always request written assurance from the source that donors of embryos and/or gametes used to create embryos consented to the type of research being proposed. If a human embryonic stem cell line is on the current NIH registry of approved lines, no further documentation is needed.

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Links

[1] <http://stemcells.nih.gov/Pages/Default.aspx>

[2] <https://www.cirm.ca.gov/>

[3] http://grants.nih.gov/stem_cells/registry/current.htm

[4]

https://www.cirm.ca.gov/sites/default/files/files/funding_page/CIRM_Guidance_NIH_Registry_Revised_APR10_0.pdf

[5] <https://www.cirm.ca.gov/our-funding/acceptably-derived-embryonic-stem-cell-lines>

[6] <http://www.cirm.ca.gov/CIRMCellLines>

[7] <http://stemcells.nih.gov/research/registry/>

[8] <http://industry.ucsf.edu/icd/home.html>

[9] <http://ita.ucsf.edu/researchers/mta>