

Comparison of Old and New Human Embryonic Stem Cell (hESC) NIH Guidelines (3-11-2010)

This summary documents the hESC practices at UNMC under the old NIH Guidelines, outlines the new NIH Guidelines and details the impact of the proposed changes at UNMC. President Obama issued an Executive Order on March 9, 2009 that overturned the Executive Order of President Bush, issued on August 9, 2001. The new directive also required the NIH to develop new Guidelines for hESC use with federal funds. After a period of review and comment, the final Guidelines were released on July 6, 2009. The new Guidelines were modeled after the National Academy of Sciences recommendations and previous NIH Guidelines. They retain the current ban on federal support for creating or destroying embryos. They reaffirm the current prohibition against cloning (SCNT). They establish a new NIH Stem Cell Registry and Advisory Committee to the Director (ACD) with a process for potential approval of hESC lines produced prior to implementation of these new guidelines (July 7, 2009). For future approvals, they impose much more rigorous standards for donor informed consent than existed under the Bush order. The major changes and impact of the changes are summarized in the following table where UNMC status under the old guidelines and UNMC status under the new guidelines are compared. These comparisons presume no changes in Nebraska State Law from what is in LB 606 and continuation of the current BOR policy from 2001.

	Under Old NIH Guidelines	Under New NIH Guidelines
Effect on UNMC Research Enterprise		
Ability to obtain new NIH grants using the new hESC lines	No	Yes
Opportunity to collaborate with researchers outside NE using the new lines	No	Yes
Ability to obtain <i>new</i> NIH grants for the "Bush Approved" hESC lines	Yes	<i>To be reviewed by ACD*</i>
Facilitates Recruitment of ALL faculty, staff and students	No	Yes
Facilitates Retention of ALL faculty, staff and students	No	Yes
Requirement to report hESC use to NU President	Yes	Yes
Institutional Review Board (IRB) review process required for use of hESC	Yes	Yes
Compatible with Nebraska state law (LB606)	Yes	Yes
Participation in Adult Stem Cell research (including cord blood & placenta)	Yes	Yes
Participation in Induced Pluripotent Stem Cell (iPSC) research	Yes	Yes
Federal Requirements for Approval of hESC Lines		
Prohibits creation or destruction of embryos with NIH support	Yes	Yes
Prohibits creation of embryos solely for research	Yes	Yes
Prohibits creation of embryos by research cloning (SCNT) with NIH support	Yes	Yes
Informed Consent requirements for donation of embryos for research. **	Limited	Extensive
- Requires donor to be informed of options for embryos	No	Yes
- Requires description of what happens to the embryos in the process of cell line derivation	No	Yes
- Requires that donors not receive any financial or other benefit from any commercial development arising from the research	No	Yes
Only allows hESC lines created prior to August 9, 2001	Yes	No
<i>Establishes a process for including new approved hESC lines in NIH registry</i>	<i>No</i>	Yes
Only allows use "... if the cells were derived from human embryos that were created for reproductive purposes [IVF], were no longer needed for this purpose, [and] were donated for research purposes..."	Yes	Yes
Prohibits offering any inducements for donation of embryos	Yes	Yes
Differences Between Old and New hESC Lines		
Number of existing and approved hESC lines <u>available</u> for NIH research	21	Hundreds
Number of existing and approved hESC lines <u>widely used</u> for NIH research	2	Hundreds
Number of "Bush approved" hESC lines used at UNMC for basic research	2	2*
hESC lines representative of the general population	Few	Many
Utility of the available hESC lines	Poor	Excellent
hESC lines contaminated by mouse cells	Yes	No
Number of embryos destroyed at UNMC for research purposes?	NONE	NONE

* Currently, only one Bush line (of 21) is included in the Registry; ** *New Informed consent requirements effective starting 7-7-2009*